From: Wehrum, Bill [Wehrum.Bill@epa.gov]

**Sent**: 5/10/2019 7:57:24 PM

To: Wehrum, Bill [Wehrum.Bill@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Davis, Alison

[Davis.Alison@epa.gov]; Sasser, Erika [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Wayland, Richard [Wayland.Richard@epa.gov]; Terry, Sara [Terry.Sara@epa.gov];

Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; McKinney, Voronina [mckinney.voronina@epa.gov]; Villahermosa,

Latisha [villahermosa.latisha@epa.gov]; Mozingo, Kristal [Mozingo.Kristal@epa.gov]; Idsal, Anne

[idsal.anne@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov]

CC: Rakosnik, Delaney [rakosnik.delaney@epa.gov]; Woods, Clint [woods.clint@epa.gov]

Subject:Review Willowbrook Risk Assessment and Plans for May 29 MeetingAttachments:Wehrum Meeting Request: Willowbrook/Lake County EtO ActivitiesLocation:WJC - N 5400 - Video with RTP Ex. 6 Personal Privacy (PP)

**Start**: 5/22/2019 6:00:00 PM **End**: 5/22/2019 7:00:00 PM

Show Time As: Busy

**TO:** Bill Wehrum, Anne Idsal, Peter Tsirigotis, Alison Davis, Erika Sasser, Kelly Rimer, Mike Koerber, Darcie Smith, Kristen Bremer, Ned Shappley, Lewis Weinstock, Laura McKelvey, Holly Wilson, Richard Wayland

Wehrum Meeting Request: Willow... From: Wilson, Holly [Wilson.Holly@epa.gov]

**Sent**: 5/7/2019 10:37:20 PM

To: Wilson, Holly [Wilson.Holly@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Terry, Sara [Terry.Sara@epa.gov];

Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; sbucha3@uic.edu; Bremer, Kristen [Bremer.Kristen@epa.gov]; kim.biggs@illinois.gov; jdurocher@indianheadpark-IL.gov; Srikant Rao [mslrao71@gmail.com]; Urszula Tanouye [urszula.tanouye@gmail.com]; Victor Simon [vsimon@gower62.com]; Smith, Darcie [Smith.Darcie@epa.gov]; Dr. Tiefu Shen: [tiefu.shen@illinois.gov]; Kyle.Garner@Illinois.gov; Douglas Pollock [DPOLLOCK@BURR-RIDGE.GOV];

Roche, Laura [Laura.Roche@Illinois.Gov]; Frost, Brad [Brad.Frost@Illinois.gov]; Cuculich, Thomas [Thomas.Cuculich@dupageco.org]; Shappley, Ned [Shappley.Ned@epa.gov]; Dunn, Matthew

[MDunn@atg.state.il.us]; Kristi Celico [kcelico@gmail.com]; mna9@cdc.gov; Nam, Ed [nam.ed@epa.gov]; Prentiss,Tamara [tprentis@hinsdale86.org]; Karen J. Ayala [kayala@dupagehealth.org]; Ward, Hillary

[Ward.Hillary@epa.gov]; Beckmann, Ronna Erin [beckmann.ronna@epa.gov]; Gayle Neal [gneal@willowbrook.il.us]; mkj5@cdc.gov; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Kottmeyer, Nick [Nick.Kottmeyer@dupageco.org]; Bendinelli, Angela [ABendinelli@dupageco.org]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Margaret Donnell [Margaret.Donnell@HISCOX.com]; Furey, Eileen [furey.eileen@epa.gov]; Kelley, Jeff [kelley.jeff@epa.gov]; Singer, Joshua [Singer.Joshua@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov];

Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Hart, Greg [Greg.Hart@dupageco.org]; Hinz, Joy

[Joy.Hinz@dupageco.org]; Renehan, Julie [Julie.Renehan@dupageco.org]; Walts, Alan [walts.alan@epa.gov]; Cutrona, Jennifer L [jennifer.cutrona@gdit.com]; Evan Walter [EWalter@burr-ridge.gov]; Village Administrator

[villageadmin@willowbrook.il.us]

**CC**: Rimer, Kelly [Rimer.Kelly@epa.gov]

Subject: Willowbrook public meeting planning call. 1-866-299-3188 passcode | Ex. 6 Personal Privacy (PP)

Attachments: Willowbrook public meeting planning call. 1-866-299-3188 passcode Ex. 6 Personal Privacy (PP) Sentle Reminder; Untitled

Attachment; Willowbrook Open House Resource Tables Draft 5\_7\_2019.pdf; 5.29 Willowbrook Meeting Draft

Agenda 5\_4\_19.pdf

Location: RTP-C400A-Max40/RTP-Bldg-C

**Start**: 5/9/2019 3:00:00 PM **End**: 5/9/2019 4:00:00 PM

Show Time As: Busy

Recurrence: Weekly

every 2 week(s) on Thursday from 11:00 AM to 12:00 PM

Gentle Reminder

From: Wehrum, Bill [Wehrum.Bill@epa.gov]

**Sent**: 4/8/2019 8:19:51 PM

To: Wehrum, Bill [Wehrum.Bill@epa.gov]; Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Davis, Alison

[Davis.Alison@epa.gov]; Wayland, Richard [Wayland.Richard@epa.gov]; Sasser, Erika [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Terry, Sara [Terry.Sara@epa.gov];

Smith, Darcie [Smith.Darcie@epa.gov]; Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Bremer, Kristen

[Bremer.Kristen@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Strum, Madeleine [Strum.Madeleine@epa.gov]; Wilson,

Holly [Wilson.Holly@epa.gov]; Hemby, James [Hemby.James@epa.gov]; McKinney, Voronina

[mckinney.voronina@epa.gov]; Villahermosa, Latisha [villahermosa.latisha@epa.gov]; Mozingo, Kristal

[Mozingo.Kristal@epa.gov]; Ward, Hillary [Ward.Hillary@epa.gov]

**CC**: Woods, Clint [woods.clint@epa.gov]

Subject: Willowbrook/EtO issues

Attachments: Wehrum Meeting Request: Emailing: EtO Discussion - Wehrum RTP April 16 2019.docx

Location: WJC - N 5400 + Ex. 6 Personal Privacy (PP)

**Start**: 4/16/2019 6:00:00 PM **End**: 4/16/2019 6:45:00 PM

Show Time As: Busy

**TO:** Bill Wehrum, Peter Tsirigotis, Alison Davis, Richard Wayland, Erika Sasser, Kelly Rimer, Mike Koerber, Sara Terry, Darcie Smith, laura McKelvey, Kristen Bremer, Doris Chen, Madeleine Strum, Holly Wilson, Jason Hemby

Wehrum Meeting Request: Emailin...

From: Mckelvey, Laura [Mckelvey.Laura@epa.gov]

**Sent**: 3/29/2019 1:44:04 PM

To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Newton, Cheryl [Newton.Cheryl@epa.gov]; Kelley, Jeff

[kelley.jeff@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]; Nam, Ed [nam.ed@epa.gov]; Davis, Alison

[Davis.Alison@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]; Cortelyou-

Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; RTP-OAQPS-919-541-4557-

OID/Phone-Line/RTP-OAQPS-BLDG-C [RTP-OAQPS-919-541-4557-OID@epa.gov]; Terry, Sara [Terry.Sara@epa.gov];

Smith, Darcie [Smith.Darcie@epa.gov]; Singer, Joshua [Singer.Joshua@epa.gov]; Sieffert, Margaret

[Sieffert.Margaret@epa.gov]; Deamer, Eileen [deamer.eileen@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Furey,

Eileen [furey.eileen@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]

CC: Beckmann, Ronna Erin [beckmann.ronna@epa.gov]; Williams, Felicia [Williams.Felicia@epa.gov]; Thiede, Kurt

[thiede.kurt@epa.gov]

Subject: Willowbrook meeting planning (Internal EPA) Ex. 6 Personal Privacy (PP) passcode required

Attachments: Willowbrook2proposed meeting outline422019.ad mk.docx

Location: 430

**Start**: 4/9/2019 8:00:00 PM **End**: 4/9/2019 9:00:00 PM

Show Time As: Busy

#### Hi folks,

Please see the attached proposal for the meeting on in Willowbrook on the 29<sup>th</sup> of May. On today's call I would like to discuss this and determine the specific rolls for Region 5 in the meeting. Note this will need to be a short call so we can prepare for the webinar.

Thanks Laura

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 4/8/2019 3:13:27 PM

To: Davis, Alison [Davis.Alison@epa.gov]; Schiermeyer, Corry [schiermeyer.corry@epa.gov]; Harlow, David

[harlow.david@epa.gov]; Woods, Clint~[woods.clint@epa.gov]; McFaul, Jessica~[mcfaul.jessica@epa.gov]; Rimer, and the state of the sta

Kelly [Rimer.Kelly@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Grantham, Nancy [Grantham.Nancy@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; DeLuca, Isabel

[DeLuca.Isabel@epa.gov]; Millett, John [Millett.John@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

CC: Sasser, Erika [Sasser.Erika@epa.gov]; Drinkard, Andrea [Drinkard.Andrea@epa.gov]

**Subject**: Backgrounder on ethylene oxide

Attachments: Internal. Briefing for Corry Schiermeyer 4.8.19.pptx

Location: Video with RTP; DC team please meet in WJCN 5400; RTP team please meet in RTP-C-430

**Start**: 4/8/2019 7:15:00 PM **End**: 4/8/2019 8:00:00 PM

Show Time As: Busy

OAQPS and OAR will provide Corry a backgrounder on ethylene oxide, along with an overview of OAR and the regions are doing to address ethylene oxide emissions.

Copies will be available at the meeting for people in DC

Tsirigotis, Peter [Tsirigotis.Peter@epa.gov] From:

2/11/2019 4:59:26 PM Sent:

To: Tsirigotis, Peter [Tsirigotis.Peter@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Sasser, Erika

> [Sasser.Erika@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Lassiter, Penny [Lassiter.Penny@epa.gov]; Witt, Jon [Witt.Jon@epa.gov]; Caparoso, Jennifer [Caparoso.Jennifer@epa.gov]; Davis,

Alison [Davis.Alison@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov]; Mckelvey, Laura

[Mckelvey.Laura@epa.gov]; Rodman, Sonja [Rodman.Sonja@epa.gov]; Ward, Hillary [Ward.Hillary@epa.gov];

Bremer, Kristen [Bremer.Kristen@epa.gov]; Fruh, Steve [Fruh.Steve@epa.gov]; Shine, Brenda

[Shine.Brenda@epa.gov]; Johnson, Steffan [johnson.steffan@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov];

Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Chen, Xi [Chen.Xi@epa.gov]; Thurman, James

[Thurman.James@epa.gov]; Strum, Madeleine [Strum.Madeleine@epa.gov]; Jones, Rhea [Jones.Rhea@epa.gov];

Hollingsworth, Terri [Hollingsworth.Terri@epa.gov]; Long, Pam [Long.Pam@epa.gov]; Terry, Sara

[Terry.Sara@epa.gov]; McBrian, Jenia [McBrian.Jenia@epa.gov]; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]

CC: Perry, Nancy [Perry.Nancy@epa.gov]; Hunt, Virginia [Hunt.Virginia@epa.gov]; Mozingo, Kristal

[Mozingo.Kristal@epa.gov]

Subject: Continued Discussion: Pre-Brief: Update on EtO -related Activities for Individual Facilities

Attachments: EtO Update Pager for Wehrum Feb 2019.docx

RTP-OAQPS-C401A-OD-IO-only/RTP-OAQPS-BLDG-C/Restricted; Call In: Ex. 6 Personal Privacy (PP) Location:

Start: 2/13/2019 8:30:00 PM End: 2/13/2019 9:15:00 PM

Show Time As: Busy

02/13/19: Materials attached.

02/11/19: Rescheduled to Wed., 2/13 at 3:15 pm at HEID request.

Scheduled 02/11/19 for Tuesday, 2/12 at 1:30 pm.

#### Message

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 5/2/2019 2:40:32 PM

To: Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: FW: 5.29 Willowbrook Meeting Draft Agenda.docx **Attachments**: 5.29 Willowbrook Meeting Draft Agenda.docx

From: Wilson, Holly

Sent: Wednesday, May 01, 2019 2:40 PM

To: Mckelvey, Laura < Mckelvey.Laura@epa.gov>; Davis, Alison < Davis.Alison@epa.gov>

Subject: 5.29 Willowbrook Meeting Draft Agenda.docx

Here is what we have so far.

Holly

#### Message

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 5/22/2019 2:52:06 PM

To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Ward, Hillary [Ward.Hillary@epa.gov]; Koerber, Mike

[Koerber.Mike@epa.gov]

CC: Wilson, Holly [Wilson.Holly@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

Subject: RE: Sterigenics risk assessment for Wehrum 05 22 19 to Mike.docx Attachments: 5.29 Willowbrook Meeting Draft Agenda as of 5 22 19MK.AD.docx

#### Helps to attach it

From: Mckelvey, Laura

Sent: Wednesday, May 22, 2019 10:31 AM

To: Ward, Hillary <Ward.Hillary@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>

Cc: Wilson, Holly < Wilson. Holly@epa.gov>; Davis, Alison < Davis. Alison@epa.gov>; Bremer, Kristen

<Bremer.Kristen@epa.gov>

Subject: RE: Sterigenics risk assessment for Wehrum 05 22 19 to Mike.docx

Here's the agenda with Mike's change in it.

From: Ward, Hillary

Sent: Wednesday, May 22, 2019 10:28 AM

To: Koerber, Mike < Koerber. Mike@epa.gov >

Cc: Mckelvey, Laura < Mckelvey, Laura@epa.gov >

Subject: RE: Sterigenics risk assessment for Wehrum 05 22 19 to Mike.docx

Ok thanks. Do you have the latest agenda from Laura? I'd like to send both docs at the same time.

Hillary Ward

USEPA, Office of Air Quality Planning and Standards

(919)541-3154

From: Koerber, Mike

Sent: Wednesday, May 22, 2019 10:24 AM To: Ward, Hillary < Ward, Hillary @epa.gov>

Subject: Fwd: Sterigenics risk assessment for Wehrum 05 22 19 to Mike.docx

#### Sent from my iPhone

Begin forwarded message:

From: "Rimer, Kelly" <Rimer.Kelly@epa.gov>
Date: May 22, 2019 at 10:06:49 AM EDT
To: "Koerber, Mike" <Koerber.Mike@epa.gov>

Cc: "Morris, Mark" < Morris. Mark@epa.gov >, "Smith, Darcie" < Smith. Darcie@epa.gov >, "Terry, Sara"

<Terry.Sara@epa.gov>

Subject: Sterigenics risk assessment for Wehrum 05 22 19 to Mike.docx

Mike,

Here for your review is the revised pager for Bill.

Decision we would like include:

# Ex. 5 Deliberative Process (DP)

Thanks Kelly

#### Message

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 3/1/2019 4:47:13 PM

To: Smith, Darcie [Smith.Darcie@epa.gov]; Koerber, Mike [Koerber.Mike@epa.gov]; Mckelvey, Laura

[Mckelvey.Laura@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: RE: Residential Exposure limits and EtO usage questions

Is that Jessica? I sent her a note, too

From: Smith, Darcie

Sent: Friday, March 01, 2019 10:11 AM

**To:** Koerber, Mike <Koerber.Mike@epa.gov>; Mckelvey, Laura <Mckelvey.Laura@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>

**Subject:** RE: Residential Exposure limits and EtO usage questions

I have a staff contact. I can ask her who the appropriate person would be.

Darcie Smith U.S. EPA/OAQPS/ATAG 919.541.2076

smith.darcie@epa.gov

From: Koerber, Mike

Sent: Friday, March 01, 2019 9:38 AM

**To:** Mckelvey, Laura < <a href="Mckelvey.Laura@epa.gov">Mckelvey.Laura@epa.gov">Mckelvey.Laura@epa.gov</a>; Bremer, Kristen < <a href="Bremer.Kristen@epa.gov">Bremer, Kristen@epa.gov</a>; Davis, Alison@epa.gov</a>; Smith, Darcie < <a href="Smith.Darcie@epa.gov">Smith.Darcie@epa.gov</a>>

Subject: FW: Residential Exposure limits and EtO usage questions

Do we have a contact at OCSPP that we can refer her to (re: Question 1)?

From: Ex. 6 Personal Privacy (PP) @gmail.com>

**Sent:** Thursday, February 28, 2019 6:51 PM **To:** Koerber, Mike < Koerber.Mike@epa.gov>

Subject: Residential Exposure limits and EtO usage questions

#### Hi Mike-

I am still trying to track down some information and hope you can help.

- 1. Who is in charge of setting a residential exposure limit? Is this part of your risk assessment? If not, when will this be completed?
- 2. I was hoping to have the EtO usage numbers you acquired recently from sterigenics? And if you did not obtain them, what is the procedure to do so?

Thanks,

Jen

https://cdn.fbsbx.com/v/t59.2708-21/50365749\_245403633012015\_4809445579958517760\_n.pdf/2014-March-EPA-

 $\frac{Pesticide-Ethylene-Oxide-Final-Work-Plan-EPA-HQ-OPP-2013-0244-0017-}{2.pdf?\_nc\_cat=110\&\_nc\_ht=cdn.fbsbx.com\&oh=2b2ddda215cbf98d703aa5a8ae34db0d\&oe=5C7A9516\&dl=1$ 

#### Message

From: Mckelvey, Laura [Mckelvey.Laura@epa.gov]

**Sent**: 5/29/2019 1:50:08 PM

To: Terry, Sara [Terry.Sara@epa.gov]; Long, Pam [Long.Pam@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov];

Koerber, Mike [Koerber.Mike@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Bremer, Kristen

[Bremer.Kristen@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Davis, Alison [Davis.Alison@epa.gov];

EtO [EtO@epa.gov]; Gmyr, Joanna [Gmyr.Joanna@epa.gov]

Subject: Fwd: FYI

Attachments: Sterigenics+EO+Sources+Release+5.29.19.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: Jennifer McConahy < Ex. 6 Personal Privacy (PP)

Date: May 29, 2019 at 8:44:41 AM CDT

To: Mckelvey.Laura@epa.gov

Subject: FYI

https://static1.squarespace.com/static/5b8457322714e5cbd33c889a/t/5cee5844e2c48339d863aacd/1559124036645/Sterigenics+EO+Sources+Release+5.29.19.pdf



## STERIGENICS HIGHLIGHTS IMPORTANT FACTS REGARDING ETHYLENE OXIDE EMISSIONS

Vehicle EO Emissions in DuPage County 18 Times Greater Than Emissions from Willowbrook Facility

EO Emissions from Recent Construction and Diesel Generator Near Willowbrook Facility Likely Captured in EPA Monitoring

Recent Research Provides New Perspectives Regarding Health Risks of EO Emissions

May 29, 2019 – Chicago, IL – Sterigenics, a leading provider of mission-critical sterilization services using only processes registered with the Food & Drug Administration for sterilizing certain medical devices, today released important new details regarding sources of ethylene oxide (EO) emissions in the Chicago area and highlighted new, independent, peer-reviewed research which provides new perspectives regarding the potential health risks of EO.

An independent analysis (summary found <a href="here">here</a>) conducted in the Chicago area found that vehicles release approximately 52,000 pounds of EO in the area per year. Furthermore, vehicles alone account for approximately 6,800 pounds of EO emissions in DuPage County per year. By comparison, the Sterigenics Willowbrook facility emitted approximately 380 pounds of EO per year when it was most recently operating.

Phillip Macnabb, President of Sterigenics said, "As the U.S. EPA has already indicated, there are multiple sources of EO in the Willowbrook area. EO emissions from vehicles in DuPage County are approximately 18 times greater than the amount of EO released by the Willowbrook facility, clearly indicating that cars and trucks are a significant contributor to EO levels in the air around Willowbrook. Our research also shows that, in addition to vehicles, recent construction and the operation of a diesel generator near our Willowbrook facility likely contribute to EO emissions measured by the U.S. EPA in its ambient air monitoring program."

Sterigenics also highlighted the findings of two recent studies which examined the potential health risks of EO. A study published in the International Journal of Environmental Research and Public Health (found <a href="https://example.com/here">here</a>) reevaluated the historical exposures to EO among sterilization workers in the National Institute of Occupational Safety and Health (NIOSH) study cohort. The NIOSH cohort study findings were relied upon by the U.S. EPA in its 2016 IRIS risk assessment. The review found that the trend in EO exposures during the study period was opposite the trend indicated in the NIOSH study "suggesting that the US EPA's exclusive reliance on the NIOSH cohort to estimate EO cancer risk should be re-examined."

Additionally, a recent study appearing in The International Archives of Occupational and Environment Health (IAOEH) conducted a systematic literature review and meta-analysis of studies of cancer risks among workers exposed to EO (summary found <a href="here">here</a>). Based on their review, the researchers concluded that the most recent and informative studies on the topic "do not support the conclusion that exposure



to EO during production or use in sterilization processes" is associated with an increased risk of lymphohematopoietic cancers (LHC) or breast cancer.

Macnabb continued, "Establishing sound public policy to protect the citizens in our communities requires accurate information and reliable data. These recent studies examine important elements regarding the sources and potential health risks of EO and provide critical data that are essential in establishing the best policy to keep the public safe. Sterigenics remains committed to working with regulators, legislators and Illinois public officials to evolve regulations and continuously improve our operations in the ongoing interest of public safety."

###

For more information, please contact:

media@sterigenics.com

From: Victor Simon [vsimon@gower62.com]

**Sent**: 12/10/2018 6:28:08 PM

**To**: Mckelvey, Laura [Mckelvey.Laura@epa.gov]

CC: Frank Trilla [ftrilla@willowbrook.il.us]; Tim Halik [thalik@willowbrook.il.us]; Davis, Alison [Davis.Alison@epa.gov];

Koerber, Mike [Koerber.Mike@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Cortelyou-Lee, Jan [Cortelyou-

Lee.Jan@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: Re: Link to the first round of monitoring data

Thank you, Laura. I'll be sure to keep an eye out for the webinar and think that your timeline for the calls starting up again later is fine.

Dr. Victor Simon III
Superintendent of Schools

Gower School District 62 7700 Clarendon Hills Rd., Willowbrook, IL 60527 (P) 630-986-5383 www.gower62.com

On Mon, Dec 10, 2018 at 7:28 AM Mckelvey, Laura < Mckelvey.Laura@epa.gov > wrote:

Thanks Dr. Simon we can regroup here and discuss this suggestion I think your feedback is very helpful. We will be hosting a webinar soon so stay tuned for that information. I was not planning on another planning group meeting until we got closer to our next in person meeting. I thought we could start up again in early January. But if you think it would be helpful to keep meeting sooner I'm happy to host them.

Laura Sent from my iPhone

On Dec 7, 2018, at 6:30 PM, Victor Simon <<u>vsimon@gower62.com</u>> wrote:

Laura, as you know, we have been posting and linking information/updates in our school community and have also been directing traffic to the Willowbrook Village site as they have been (maybe up until now), the most direct and most current source of information. As this issue has evolved, the EPA site - as shared in your latest email - in my opinion is the new Number 1 source (and probably should be). Particularly given the fact that the EPA site was updated with the testing data and then the group was notified. I appreciate the update. I also want you to know that the number of various community members in your distribution list began posting immediately and in a variety of places. Generally this is fine and expected. However, there may have been some unintended consequences such as 'people finding out' before we 'could produce and share a formal communication' leaving some finger pointing and the potential for mistrust. Again no real complaint here, but I do see an opportunity for improvement; especially if you could establish some cadence to when data will be posted on the EPA site. For example, if there was a commitment to a weekly update on Fridays or twice a week, etc., that could easily be broadcast by all community partners and help direct traffic, etc....

I understand that there could be a scenario of 'no new info' (which can easily be addressed as such for that week) or an 'emergency announcement' (which is an entirely different issue). But generally speaking, if we are about to get into the data being posted over the course of the next three months, we can choose to post sporadically, daily, weekly. I'd suggest weekly, but that will ultimately be an EPA decision. Of course, there are going to be all levels of engagement in terms of community members closely monitoring and refreshing that site for the latest info... I copied Mayor Trilla and Village Administrator Halik as they have been instrumental in keeping the larger community updated and may want to weigh in. I chose not to 'reply all' for a reason.

Again, no complaint. Glad to have the information. Are you expecting to host another call anytime soon? I'm not sure if one was held this week or not to debrief the forum and/or discuss next steps... I want to be sure to remain included if such calls are to continue...

As an FYI, this is the resulting communication we sent today.

## Gower School District Community Newsletter December 7, 2018

View this email in your browser

#### Important Update: Sterigenics Willowbrook Facility

The U.S. EPA has posted results for three days of air quality monitoring around the Sterigenics Willowbrook (November 13, 16 and 19, 2018). Information about the results, including a link to the interactive map and a link to FAQs about the results, is available at this link: <a href="https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update">https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update</a>. It is important to recognize that the EPA is expected to continue to post updates related to the issue at this website directly. Gower School District Officials will continue to provide updates as they are made available and encourage members of our community to visit the EPA website and/or the Willowbrook Village website at <a href="https://www.willowbrookil.org">www.willowbrookil.org</a> for the most direct and updated information. In summary:

- EPA Monitors detected ethylene oxide in the air at the two sites closest to the Sterigenics facility.
- EPA Monitors did not detect ethylene oxide at the six community-oriented sites -- including those at schools and in residential areas.
- EPA plans to continue monitoring in the Willowbrook area for three months and will continue to post data as it becomes available.

 EPA will conduct a full assessment of risk from ethylene oxide in Willowbrook, which is expected to be completed by Spring 2019.

Although it may be premature to draw conclusions related to the most recent data posted by the EPA, District Officials will re-route buses, effective immediately and using Willowbrook Center Parkway exclusively, to bypass the area at which ethylene oxide has been detected (Quincy St. and Midway Dr.). The current information from the EPA may not support a claim of an immediate health risk to our students or our drivers, but it is enough to support a decision being made out of an abundance of caution. We expect to learn more and will respond accordingly as the EPA continues its monitoring of the area and carries out a full risk assessment in our community.

With continued concern,

Victor Simon
Superintendent of Schools

Dr. Victor Simon III
Superintendent of Schools

Gower School District 62 7700 Clarendon Hills Rd., Willowbrook, IL 60527 (P) 630-986-5383 www.gower62.com

On Fri, Dec 7, 2018 at 11:43 AM Mckelvey, Laura < Mckelvey. Laura@epa.gov > wrote:

Hi folks,

Please find the initial data from U.S. EPA's air quality monitoring are posted. Information about the results, including a link to the interactive map and a link to FAQs about the results, is available at this link: <a href="https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update">https://www.epa.gov/il/sterigenics-willowbrook-facility-latest-update</a>

	iding out the informate any questions.	tion of the first webinar so	oon. Please feel free to c
me ii you nave	any questions.		
Thanks			
Laura			

From: Koerber, Mike [Koerber.Mike@epa.gov]

**Sent**: 5/16/2019 7:19:04 PM

To: Davis, Alison [Davis.Alison@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

CC: Noonan, Jenny [Noonan.Jenny@epa.gov]

Subject: Fwd: Sterigenics Willowbrook Ambient Air Monitoring

Attachments: Sterigenics Letter to EPA re Ambient results 10MAY2019.pdf; ATT00001.htm; Mobile Source Attachment.pdf;

ATT00002.htm

## Ex. 5 Deliberative Process (DP)

Mike

Sent from my iPhone

Begin forwarded message:

From: "Macnabb, Philip" < PMacnabb@sterigenics.com>

Date: May 10, 2019 at 1:40:41 PM EDT

To: "wehrum.bill@epa.gov" <wehrum.bill@epa.gov>

Cc: "Woods, Clint" <woods.clint@epa.gov>, "Koerber, Mike" <Koerber.Mike@epa.gov>, "tcr@vnf.com"

<tcr@vnf.com</td>, "Hoffman, Kathy" < KHoffman@sterigenics.com</td>

Subject: Sterigenics Willowbrook Ambient Air Monitoring

Bill

Please find attached letter and additional report regarding concerns the company has around the results of ambient air monitoring conducted by the EPA around our Willowbrook, Illinois facility. We would be happy to have a discussion via phone or in person regarding this topic.

Thank you

#### Philip Macnabb

#### President

Sterigenics, A Sotera Health company 2015 Spring Rd, Suite 650 Oak Brook, IL 60523 pmacnabb@sterigenics.com

www.sterigenics.com

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This e-mail and any files transmitted with it may contain privileged and/or confidential information. If you believe this e-mail or any of its attachments were not intended for you, you must not use, distribute, forward, print or copy this e-mail or any attached files. If you have received this e-mail in error, please notify the sender by reply e-mail and then immediately delete the email and all attachments.



#### TECHNICAL WHITE PAPER

Application of the USEPA National Emissions Inventory and USEPA MOVES Model to Characterize Ethylene Oxide Contributions from Vehicle Sources in the Chicago Metropolitan Planning Area

Christian Lindhjem, PhD1 & Robert P. DeMott, PhD2

<sup>1</sup> Ramboll, Mobile Source Modeling, Novato, CA

Release Date: 8 May 2019

Ethylene oxide (EtO) is a product of incomplete combustion produced by vehicles using hydrocarbon fuels. We evaluated information from recent testing completed for EtO in the exhaust emissions from diesel and gasoline-powered vehicles. We combined the information from this testing on the fraction of EtO in overall emissions with information from a USEPA compilation of overall vehicle emissions, the National Emissions Inventory (NEI), covering the Chicago Metropolitan Agency for Planning (CMAP) area and estimates of the fraction of vehicles with and without catalytic converters from the USEPA MOVES model to estimate vehicle EtO emissions for each county in the CMAP area.

In summary, based on our modelling annual ethylene oxide emissions from vehicle exhaust in the metropolitan planning area are approximately 52,000 pounds. Vehicles in Cook County make the largest contribution, approximately 26,600 lb/year. Vehicles in Dupage County make the second largest contribution to the area at approximately 6800 lb/yr.

#### **Emission Testing Results**

For information on ethylene oxide production by vehicle engines, we relied on recent results of testing by Montrose Air Quality Services. Montrose measured ethylene oxide (EtO) and carbon dioxide (CO2) emissions in the exhaust from a gasoline and a diesel truck<sup>1</sup>. Measurements were made before and after the exhaust passed through the catalytic aftertreatment devices for the respective vehicles. For the diesel truck results, we used this study design element to characterize separately emissions from pre-2007 trucks, years before the prevalent use of catalytic converters on diesel truck, and post-2007 trucks, which typically require catalytic converters to meet emissions standards. We used the results measured before the catalytic converter in the test truck to represent older, uncatalyzed trucks and the results measured after the catalytic converter to represent newer trucks expected to have catalyzed emissions.

Ramboll 10150 Highland Manor Drive, Suite 440, Tampa, FL  $\,$  33610 V +1  $\,$  813.628.4325 ramboll.com

<sup>&</sup>lt;sup>2</sup> Ramboll, Product Safety & Stewardship, Tampa, FL

<sup>&</sup>lt;sup>1</sup> Montrose Air Quality Services, LLC 2019. "SOURCE TEST REPORT 2019 Ethylene Oxide Gas and Diesel Truck Study," Prepared For: Sterigenics International LLC

From the measured results for the concentrations of CO2 and EtO, we calculated the ratio of EtO to CO2. This ratio is useful because CO2 emissions for a geographic area can be estimated from the NEI information. The ratio can then be used to convert these to estimated EtO emissions for the corresponding area. For situations where the EtO emissions concentration was lower than the reported detection limit for the testing, we used a surrogate value of ½ the detection limit. Key information from the Montrose testing is shown in Table 1.

Table 1. Engine Test Results and EtO/CO2 Ratios

Result	Average – Gasoline	Average - Diesel
CO2 (%)	13.6	2.7
(70)	13.0	2.7
Before Catalyst		
	1.24	101
EtO (ppb)	(1/2 Detection Limit)	
EtO / CO2 Ratio x 10 <sup>9</sup>	9.1	3740
After Catalyst		
	0.5	0.5
EtO (ppb)	(1/2 Detection Limit)	(1/2 Detection Limit)
EtO / CO2 Ratio x 10 <sup>9</sup>	3.7	18.5

#### **Mobile Source Inventory**

The NEI is EPA's compilation of emissions from fuel combustion for all counties in the U.S. We used the most recent available information, which is from calendar year 2014. We extracted the NEI information for the seven counties included in the CMAP transportation planning area as representative for the overall Chicago metropolitan area. The CMAP area includes Cook, Dupage, Kane, Kendall, Lake, McHenry and Will counties.

We used the sulfur dioxide (SO2) emissions inventories in the NEI to estimate overall fuel use by on-road and offroad diesel and gasoline powered engines and railroad locomotives. Because sulfur content was not regulated in the fuel for ship engines in 2014, we used information on oxides of nitrogen (NOx) to determine fuel consumption for commercial marine engines relative to locomotives. Having compiled an estimate of fuel consumption by county and engine type, we calculated corresponding CO2 emissions based on the federal specifications for the carbon content in gasoline and diesel fuel.

#### Fraction of Vehicles With and Without Catalytic Converters

The next step was to estimate the fraction of overall vehicles expected to release uncatalyzed emissions. Since light-duty gasoline engine vehicles have had catalytic converters since the 1981 model year or earlier, we assumed all gasoline-powered vehicles released catalyzed emissions. For diesel-powered vehicles, we assumed that onroad trucks from before the 2007 model year had uncatalyzed emissions and later model year vehicles had catalyzed emissions. This is based on the implementation of reduced emissions standards applicable with the 2007



model year that effectively required diesel particulate filters. Additional emissions controls via selective catalytic reduction (SCR) aftertreatment catalysts were routinely added beginning in 2010. Prior to 2007, diesel trucks did not widely incorporate catalytic converters. For off-road diesel vehicles, the same approach was used, only the relevant model year cutoff was primarily 2010, when the emissions reductions began to be phased in for this category of engine. Locomotives and diesel engines for ships were assumed to release uncatalyzed emissions.

To identify the CO2 emissions from specific fractions of the overall vehicle fleet that fit into each of these categories, we used the USEPA MOVES model. This model serves to identify the number and activity of vehicles by model year in a given area and estimate corresponding CO2 emissions. In order to match the source year of the CO2 emissions derived from NEI (2014), we used the fleet composition in USEPA MOVES model run for the 2014 calendar year. We tested the model for both Cook and Dupage counties and determined that the fractions of each engine type were similar (Table 2). This means that the fractions obtained are sufficiently consistent with modeled emissions to be generalized for estimating EtO in the Chicago area.

Table 2. Fraction of CO2 Production by Uncatalyzed (Older) and Catalyzed (Newer) Diesel Engines

Fleet	On-road diesel	On-road diesel		Off-road diesel	
	Pre-2007 (Without catalyst)	Post-2007 (With catalyst)	Pre-2011 (Without catalyst)	Post-2011 (With catalyst)	
Cook Co.	46.4%	53.6%	64.1%	35.9%	
DuPage Co.	46.4%	53.6%	65.6 %	34.4%	

Based on the USEPA MOVES model, 46.4% of on-road diesel truck fleets or trips is assumed to release EtO at the concentration and ratio to CO2 reflected in the Montrose measurements before the catalytic converter. The remainder (53.6% of on-road fleet or trips) is represented by the Montrose measurements after the catalytic converter.

#### **Regional EtO Emissions Estimates**

With the CO2 emissions apportioned between diesel vehicles with and without catalytic converters, we then multiplied the corresponding amount of CO2 by the ratio of EtO/CO2 for each category (with or without catalyst) to calculate an amount of EtO from each category of vehicle. Since we assumed all gasoline engines had catalytic converters, there was only one category for gasoline vehicles and the ratio from the measurement after the catalytic converter on the gasoline test truck was used.

The projected annual EtO emissions corresponding to the 2014 NEI emissions and 2014 USEPA MOVES fleet information is shown by CMAP county in shown in Table 3. The total for Dupage County is approximately 6800 lb/yr and the total for the CMAP area is approximately 52,000 lb/yr.



Table 3. Projected Ethylene Oxide Emissions (lb/yr) for Chicago Area Counties

	Diesel-Powered Fleet	Gasoline-Powered Fleet
County		
Cook	26,499	114
DuPage	6,772	28
Will	5,843	19
Lake	5,032	19
Kane	4,065	13
McHenry	2,416	8
Kendall	931	3
Total	51,558	204

We also calculated EtO emissions by engine categories included in USEPA MOVES for all of the counties combined, shown in Table 4. These estimates are again based on the 2014 emissions inventory from NEI and the 2014 fleet percentages from USEPA MOVES.

This illustrates that the on-road diesel powered fleet is the largest contributing vehicle type to EtO background at 25,655 lbs/yr. However, while the number of non-road diesel vehicles (e.g, heavy equipment) is expected to be much smaller, it is notable that the EtO contribution from this category (19,232 lb/yr) is a relatively large fraction of overall vehicular contribution. Railroad locomotives are the next largest source, albeit much lower (4122 lb/yr).

Table 4. Ethylene Oxide Emissions (lb/yr) by Engine Category for CMAP Counties

	Diesel-Powered	Gasoline-Powered
Source Category	Fleet	Fleet
Highway Diesel	25,655	
Non-Road Diesel	19,232	
Railroads*	4,122	
Marine Vessels*	910	
Other	1,639	
Highway Gasoline		194
Non-Road Gasoline		9
Highway E-85		1
Total	51,558	204

<sup>\*</sup> These engines were assumed to not use catalysts.

To illustrate the extent of potential uncertainty and the range of potential estimates, we included a bounding analysis by changing the fraction of engines assumed to have catalytic converters. A lower bound estimate of 5301 lb/yr was calculated using the assumption that all road and non-road diesel engines had catalytic converters. An upper bound estimate of 92,036 lb/yr was calculated using the assumption that no diesel engines had catalytic converters.





May 10, 2019

Hon. William L. Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 6101A
Washington, DC 20460

Re: <u>EPA Risk Assessment for Ethylene Oxide in Willowbrook, Illinois: Ambient Air</u> Monitoring Data

Dear Mr. Wehrum:

We write regarding EPA's stated intention to complete a risk assessment regarding ethylene oxide levels in the Willowbrook, Illinois area near Sterigenics' Willowbrook facility. Specifically, our concerns relate to the possibility that ambient monitoring data might be used in some manner in the analysis. As discussed below, we have significant concerns about the accuracy and significance of EPA's ambient air monitoring because of additional information the company has been able to compile. This information includes identification of ethylene oxide sources that, to our knowledge, EPA to date has not considered in its review of the Willowbrook area, and data quality issues that call into question the validity and accuracy of ambient air monitoring results.

As you know, ambient monitoring data can identify the level of a particular chemical or compound in the atmosphere at a specific location and point in time. Ambient monitoring does not, however, identify the source of the detected material. We are unaware of any effort by EPA, in collecting ambient monitoring data in Willowbrook, to secure and maintain the integrity of the monitoring locations while EPA's canisters were deployed in Willowbrook for the November to March monitoring program. In fact, we have evidence of unidentified individuals handling canisters during the test period. Similarly, we are not aware of any efforts by EPA or any of the other federal, state, and local agencies that have studied or opined on conditions in Willowbrook to identify other potential sources of ethylene oxide emissions. Sterigenics recognizes that its facility has some level of emissions, and when allowed to operate, the facility kept its emissions far below permitted levels. Nevertheless, we believe that at least some of the ambient air concentrations of ethylene oxide that EPA measured are likely from other sources.

2015 Spring Rd, Suite 650

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First, throughout the entire time period during which EPA conducted its monitoring, substantial construction activities took place immediately adjacent to EPA's monitoring canisters at the "Village Hall" location. We obtained the specifications of the materials actually used during this significant building-wide renovation project, as some building materials contain ingredients that can reasonably be expected to contain or produce ethylene oxide during use. Indeed, through testing some of the materials that were actually used at the adjacent construction site during the EPA's monitoring program, we confirmed that some materials give off significant ethylene oxide to the surrounding air. While our data are not final, as they are currently undergoing additional quality assurance testing, our efforts are ongoing. Notably, these construction activities ceased in mid-February 2019, about the same time the Willowbrook facility ceased operating.

We also know that mobile sources can have a significant impact on ambient ethylene oxide levels. Sterigenics sampled the exhaust from diesel and gasoline-powered vehicle engines, both before and after catalytic converters, for ethylene oxide. We then used information from publicly-available sources to estimate ethylene oxide emissions to the atmosphere for each of the counties in the Chicago metropolitan area. A white paper describing this analysis in greater detail is attached to this letter. As the white paper indicates, we estimated approximately 52,000 pounds of ethylene oxide emitted from vehicles in the Chicago area each year, with 6,800 of those pounds emitted in DuPage County alone:

Estimated Annual Ethylene Oxide Emissions (lbs. /yr.) in Chicago Area Counties from Mobile Sources				
County	Diesel- Powered Fleet	Gasoline- Powered Fleet	Total	
Cook	26,499	114	26,613	
DuPage	6,772	28	6,800	
Will	5,843	19	5,862	
Lake	5,032	19	5,051	
Kane	4,065	13	4,078	
McHenry	2,416	8	2,424	
Kendall	931	3	934	
Total	51,558	204	51,762	

Given the high level of traffic in the Willowbrook area and very near to the EPA's ambient sample locations in the commercial area, it is likely that vehicle emissions had a material impact on EPA's ambient air monitoring results.

Everyday sources – such as home heating furnaces, boilers, and grills – also contribute to ethylene oxide levels because common fossil-fuel sources result in ethylene oxide emissions. We have sampled the air surrounding several everyday sources of ethylene oxide,



including propane grills, wood-burning stoves, natural gas furnaces, and gasoline-powered lawn mower engines. This investigation was performed consistent with EPA methods by placing the everyday sources in an enclosure and operating them, and then sampling and analyzing air from the enclosures for ethylene oxide. Average ethylene oxide concentrations detected in the enclosure from these everyday sources were:

Source	Average Concentration (µg/m³)
Propane grills	86.7
Wood-burning stoves	84.7
Gas-powered lawn mower engines	75.3
Natural gas furnaces	0.577

A suburban community, such as Willowbrook, undoubtedly has large numbers of these everyday sources in use. The businesses and government buildings near Sterigenics' Willowbrook facility must also operate boilers and other fossil fuel-powered sources that emit similar ethylene oxide emissions. In fact, the EPA office directly behind our facility operates a diesel backup generator about 40 feet from one of the monitoring locations. The ethylene oxide emission rates from these everyday sources are large enough that they should be considered when assessing any ambient air monitoring results from the Willowbrook area.

Finally, there is a general background level of ethylene oxide. Sterigenics has demonstrated that background concentrations of ethylene oxide exist throughout the Chicago area, including in areas that are not near any known industrial ethylene oxide sources. Sterigenics commissioned Ramboll, a respected science and engineering consulting firm, to study the ambient conditions in the greater Chicagoland area. Ramboll sampled ambient air in October and November 2018 from a variety of Chicago area locations, from Golden Gate Park south of Chicago to Highland Park in the north and from Lake Michigan west out to Naperville. An independent laboratory analyzed these 76 samples and measured ethylene oxide concentrations that ranged from 0.09  $\mu$ g/m³ to 1.10  $\mu$ g/m³. The mean concentration of the October 2018 samples was 0.28  $\mu$ g/m³, and the mean concentration of the November 2018 samples was 0.21  $\mu$ g/m³. Additional information about these data is available at www.sterigenicswillowbrook.com.

If we understand correctly, EPA intends to use monitoring data in combination with modeling results in its risk assessment. However, using the ambient data and assuming that the measured values are primarily due to Sterigenics' operations introduces a very significant risk of error, particularly when both the measured values, Sterigenics' emissions, and the risk-based concentrations being targeted are all very low numbers.

In light of these and other facts, we ask that EPA pay particular attention to the following points as it addresses ambient air monitoring data in its risk assessment:



- The ethylene oxide background concentrations represent a practical minimum level that will always exist in the Willowbrook community, regardless of what permit limits or other regulations are applied to the Sterigenics facility and no matter whether the facility is permitted to re-open.
- The pervasive presence of background ethylene oxide levels calls into question the methodology used in the December 2016 IRIS assessment of ethylene oxide, since the inhalation unit risk level was set without regard to ubiquitous background concentrations of ethylene oxide.
- Ethylene oxide's presence in all communities, and from sources that are familiar to U.S. households, is a vital fact in characterizing and communicating any potential risk to residents. It is important that the public know that ethylene oxide is ubiquitous and is emitted from many common sources and items that the public uses in everyday activities.

If EPA's risk assessment is to be fair and scientifically reliable, it also must take a hard look at data quality issues and incorporate them in its analysis. The information above stresses several data quality issues that call the validity of EPA's air monitoring data for risk assessment purposes into question:

- During the sampling period, the Village's "Board and Community Center" at 825 Midway Drive underwent significant roofing and façade renovations. As described above, construction products including some of the products actually used in this renovation work contain and give off ethylene oxide. The construction work on Midway Drive located within feet of and immediately adjacent to a sampling location used by EPA and the Village for air monitoring (described as "Village Hall" in EPA's monitoring results) began in approximately November 2018 and continued through mid-February 2019.
- Sampling locations were also located close to significant trucking activity and highways, including within feet of local streets with significant numbers of trucks and cars passing, stopping, and idling. Notably, truck traffic close to commercial area EPA sampling sites in Willowbrook declined significantly following February 15, 2019.
- EPA's and the Village's sampling protocols did not include sufficient chain of custody control, in that they lacked any measures to monitor or prevent pedestrians from approaching, touching, or smoking near the monitoring canisters. In fact, there is evidence of unidentified individuals handling canisters on a day when a "high" reading occurred.



• Samples taken at EPA's Willowbrook warehouse during the sampling period, including in February 2019, were collected near a large diesel generator. While this generator does not operate every day, it did operate on the day that EPA's sampling registered the highest reading at that location. As noted above, diesel engines, particularly if uncontrolled or poorly controlled, emit significant ethylene oxide.

In addition to these particular issues, EPA should acknowledge that the science of measuring very low concentrations of ethylene oxide in air is not well-developed, and laboratories have been pushing the edge of the science in fine-tuning methods to quantify ethylene oxide with low detection limits. This can be seen in the error that EPA's laboratory made on the pre-October 2018 air samples in Willowbrook, in which the laboratory method was not able to distinguish ethylene oxide from trans-2-butene. While that particular error may have been corrected, the state of the science indicates that ambient air monitoring results should be viewed with caution.

Finally, as EPA is aware, Sterigenics has proposed an operating scenario to the State of Illinois, which includes significant engineering changes beyond the facility's already-state-of-the-art emission controls, under which the facility's average hourly emissions of ethylene oxide would be remarkably low. With these improvements, we estimate our annual emissions will be less than 1% of the estimated annual emissions from just the mobile sources in DuPage County, not considering the additional contributions from the myriad other ethylene outside sources. These improvements should be considered in any risk assessment.

We would be happy to discuss these important considerations and answer any questions you may have regarding the information presented in this letter. We would also be willing to provide additional methodological and other details regarding Sterigenics' efforts to identify ethylene oxide background concentrations, ethylene oxide emissions from everyday sources, and data quality issues related to EPA's air monitoring program. Please feel free to contact Kathy Hoffman (630-928-1758; khoffman@sterigenics.com) with any questions that you or your staff may have.

Sincerely,

Philip Macnabb

Attachment

#### Message

From: Mckelvey, Laura [Mckelvey.Laura@epa.gov]

**Sent**: 5/29/2019 1:49:20 PM

To: Terry, Sara [Terry.Sara@epa.gov]; Long, Pam [Long.Pam@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov];

Koerber, Mike [Koerber.Mike@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Bremer, Kristen

[Bremer.Kristen@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Davis, Alison [Davis.Alison@epa.gov];

EtO [EtO@epa.gov]

Subject: Fwd: FYI

Attachments: Sterigenics+Letter+to+EPA+re+Ambient+results+10MAY2019.pdf; ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: Jennifer McConahy Ex. 6 Personal Privacy (PP) <u>agmail.com</u>>

Date: May 29, 2019 at 8:44:21 AM CDT

To: Mckelvey.Laura@epa.gov

Subject: FYI

https://static1.squarespace.com/static/5b8457322714e5cbd33c889a/t/5cee58184e17b6215b12dfa 0/1559123993278/Sterigenics+Letter+to+EPA+re+Ambient+results+10MAY2019.pdf



May 10, 2019

Hon. William L. Wehrum
Assistant Administrator
Office of Air and Radiation
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 6101A
Washington, DC 20460

Re: <u>EPA Risk Assessment for Ethylene Oxide in Willowbrook, Illinois: Ambient Air</u> Monitoring Data

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Natural gas furnaces	0.577

A suburban community, such as Willowbrook, undoubtedly has large numbers of these everyday sources in use. The businesses and government buildings near Sterigenics' Willowbrook facility must also operate boilers and other fossil fuel-powered sources that emit similar ethylene oxide emissions. In fact, the EPA office directly behind our facility operates a diesel backup generator about 40 feet from one of the monitoring locations. The ethylene oxide emission rates from these everyday sources are large enough that they should be considered when assessing any ambient air monitoring results from the Willowbrook area.

Finally, there is a general background level of ethylene oxide. Sterigenics has demonstrated that background concentrations of ethylene oxide exist throughout the Chicago area, including in areas that are not near any known industrial ethylene oxide sources. Sterigenics commissioned Ramboll, a respected science and engineering consulting firm, to study the ambient conditions in the greater Chicagoland area. Ramboll sampled ambient air in October and November 2018 from a variety of Chicago area locations, from Golden Gate Park south of Chicago to Highland Park in the north and from Lake Michigan west out to Naperville. An independent laboratory analyzed these 76 samples and measured ethylene oxide concentrations that ranged from 0.09  $\mu$ g/m³ to 1.10  $\mu$ g/m³. The mean concentration of the October 2018 samples was 0.28  $\mu$ g/m³, and the mean concentration of the November 2018 samples was 0.21  $\mu$ g/m³. Additional information about these data is available at www.sterigenicswillowbrook.com.

If we understand correctly, EPA intends to use monitoring data in combination with modeling results in its risk assessment. However, using the ambient data and assuming that the measured values are primarily due to Sterigenics' operations introduces a very significant risk of error, particularly when both the measured values, Sterigenics' emissions, and the risk-based concentrations being targeted are all very low numbers.

In light of these and other facts, we ask that EPA pay particular attention to the following points as it addresses ambient air monitoring data in its risk assessment:



- The ethylene oxide background concentrations represent a practical minimum level that will always exist in the Willowbrook community, regardless of what permit limits or other regulations are applied to the Sterigenics facility and no matter whether the facility is permitted to re-open.
- The pervasive presence of background ethylene oxide levels calls into question the methodology used in the December 2016 IRIS assessment of ethylene oxide, since the inhalation unit risk level was set without regard to ubiquitous background concentrations of ethylene oxide.
- Ethylene oxide's presence in all communities, and from sources that are familiar to U.S. households, is a vital fact in characterizing and communicating any potential risk to residents. It is important that the public know that ethylene oxide is ubiquitous and is emitted from many common sources and items that the public uses in everyday activities.

If EPA's risk assessment is to be fair and scientifically reliable, it also must take a hard look at data quality issues and incorporate them in its analysis. The information above stresses several data quality issues that call the validity of EPA's air monitoring data for risk assessment purposes into question:

- During the sampling period, the Village's "Board and Community Center" at 825 Midway Drive underwent significant roofing and façade renovations. As described above, construction products including some of the products actually used in this renovation work contain and give off ethylene oxide. The construction work on Midway Drive located within feet of and immediately adjacent to a sampling location used by EPA and the Village for air monitoring (described as "Village Hall" in EPA's monitoring results) began in approximately November 2018 and continued through mid-February 2019.
- Sampling locations were also located close to significant trucking activity and highways, including within feet of local streets with significant numbers of trucks and cars passing, stopping, and idling. Notably, truck traffic close to commercial area EPA sampling sites in Willowbrook declined significantly following February 15, 2019.
- EPA's and the Village's sampling protocols did not include sufficient chain of custody control, in that they lacked any measures to monitor or prevent pedestrians from approaching, touching, or smoking near the monitoring canisters. In fact, there is evidence of unidentified individuals handling canisters on a day when a "high" reading occurred.



• Samples taken at EPA's Willowbrook warehouse during the sampling period, including in February 2019, were collected near a large diesel generator. While this generator does not operate every day, it did operate on the day that EPA's sampling registered the highest reading at that location. As noted above, diesel engines, particularly if uncontrolled or poorly controlled, emit significant ethylene oxide.

In addition to these particular issues, EPA should acknowledge that the science of measuring very low concentrations of ethylene oxide in air is not well-developed, and laboratories have been pushing the edge of the science in fine-tuning methods to quantify ethylene oxide with low detection limits. This can be seen in the error that EPA's laboratory made on the pre-October 2018 air samples in Willowbrook, in which the laboratory method was not able to distinguish ethylene oxide from trans-2-butene. While that particular error may have been corrected, the state of the science indicates that ambient air monitoring results should be viewed with caution.

Finally, as EPA is aware, Sterigenics has proposed an operating scenario to the State of Illinois, which includes significant engineering changes beyond the facility's already-state-of-the-art emission controls, under which the facility's average hourly emissions of ethylene oxide would be remarkably low. With these improvements, we estimate our annual emissions will be less than 1% of the estimated annual emissions from just the mobile sources in DuPage County, not considering the additional contributions from the myriad other ethylene outside sources. These improvements should be considered in any risk assessment.

We would be happy to discuss these important considerations and answer any questions you may have regarding the information presented in this letter. We would also be willing to provide additional methodological and other details regarding Sterigenics' efforts to identify ethylene oxide background concentrations, ethylene oxide emissions from everyday sources, and data quality issues related to EPA's air monitoring program. Please feel free to contact Kathy Hoffman (630-928-1758; khoffman@sterigenics.com) with any questions that you or your staff may have.

Sincerely,

Philip Macnabb

Attachment

#### Message

From: Koerber, Mike [Koerber.Mike@epa.gov]

**Sent**: 12/18/2018 3:19:56 PM

To: Weinstock, Lewis [Weinstock.Lewis@epa.gov]; McBrian, Jenia [McBrian.Jenia@epa.gov]; Chen, Xi

[Chen.Xi@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]; Shappley, Ned

[Shappley.Ned@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

**Subject**: Fwd: Discuss QA Issues

#### Sent from my iPhone

#### Begin forwarded message:

From: "Dyron.Hamlin@ghd.com" < Dyron.Hamlin@ghd.com>

**Date:** December 18, 2018 at 10:14:58 AM EST **To:** "Koerber, Mike" < Koerber. Mike@epa.gov >

Subject: FW: Discuss QA Issues

#### Dyron Hamlin, MS, PE, CIH | A GHD Principal

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T: 501 224 1926 | M: 501 766 1625 | E: dyron.hamlin@ghd.com 11719 Hinson Road Suite 100 Little Rock Arkansas 72212 USA | www.ghd.com

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----Original Appointment----

From: Dyron Hamlin

Sent: Monday, December 17, 2018 2:29 PM

To: Koerber, Mike

Cc: Cipriano, Renee; Benjamin Chandler; Tim Halik; Gayle Neal; 'Lucy Fraiser'

Subject: Accepted: Discuss QA Issues

When: Tuesday, December 18, 2018 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Phone Number: 202-991-0477, code=282816

Mike,

We will be on the call tomorrow to compare notes on laboratory analytical methods, results comparison between USEPA and Willowbrook, etc. We have not identified any QA issues in doing our due diligence thus far.

We've reviewed your questions, and we're certainly familiar with canisters and how they work, including pressures, etc. To cover that set of questions at the end of the report, I'll just say in short that our samples were received within appropriate pressure limits, as measured at the lab, and not on the field gauges, which is what we listed in the report, just to ensure as well as we could with field gauges that the samples did not go to ambient pressure.

In short, we're confident in the results, and the sampling procedure, which is fairly simple; we reviewed, and had our project chemist review, the results prior to publishing our report. We haven't seen any interference from compounds biasing our results high; in fact, our result at our single sample co-located with USEPA was slightly lower than the result measured by USEPA (0.576 compared to  $0.824~\mu g/m^3$ , respectively), although within measurement accuracy range (our reported accuracy is 24.7%). Our results did not specifically target trans-2-butene, as we've not identified it specifically as a potential issue; but given the interest raised by the USEPA, the lab is going to look for it and rule it out going forward.

We are also following up in this reply with the following questions and discussion points:

- 1. You mentioned for the results you've received thus far that trans-2-butene was a non-detect at all your sample locations over multiple days. Given that, do you still think your May results are skewed high and if so why?
- 2. Can you explain the increase in measured concentrations from Nov 16 to Nov 19 at the EPA warehouse and Village Hall? We know it is just one data set, but do you think there was a lab error, or is there possibly another explanation?
- 3. What was the sample quantitation limit (SQL) actually achieved during these specific sampling events?
- 4. You noted that samples not meeting identification acceptance criteria would be flagged "ND."
- a. According to the sampling plan, samples below the MDL were supposed to be flagged with "MD". Is this related to identification criteria, rather than method detection limit? I.e., was the presence of a compound identified, but determined not to be EO?
- b. I believe we've asked for chromatograms previously, and have yet to receive them. If you could provide, them, it may be helpful to our laboratory to compare notes.
- 5. Did you evaluate the meteorology conditions on your sampling days (i.e., wind direction and speed, etc.)?
- 6. What issue caused the Nov. 13 results to be invalid?
- 7. EPA's sampling plan states that EPA will work with Sterigenics to make production and EtO usage data available for correlation with ambient results. Does EPA have any information on what the Sterigenics operating conditions were on Nov. 13, 16, and 19?
- 8. Was there a reason EPA didn't deploy at the planned 8 sample locations on November 16, when we had a chance to co-locate numerous additional samples, and were only able to co-locate one?
- 9. Do you have any comments specific to the indoor/outdoor sample result differences? This is a key input to your risk assessment assumption that inside is equal to outside may not be valid.

Γhanks!
Dyron
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other person. GHD and its affiliates reserve the right to monitor and modify all email communications through their networks.

Those are a few thoughts to guide our discussion tomorrow.

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 5/25/2019 1:18:11 AM

To: Smith, Darcie [Smith.Darcie@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov]; Mckelvey, Laura

[Mckelvey.Laura@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: Risk Assessment Results for Sterigenics - Willowbrook V2.pptx **Attachments**: Risk Assessment Results for Sterigenics - Willowbrook V2.pptx

Hi everyone,

Here for your review is the draft of the presentation. Please get me comments by 2 pm tomorrow.

The speaker notes are in progress - comment on them or not. Additions and changes welcome.

# Ex. 5 Deliberative Process (DP)

## What else?

It would be easiest for me if you send me a note about what changes you want on which slide – redline strikeout on power points is a pain. But if that doesn't work for you – I can adjust - no worries.

KRISTEN – (sorry for the caps) – It needs formatting but I think that is the last thing -?maybe Sunday or Monday

The plan is to for me to get your comments, then I will turn them around ASAP and get them to Alison. She will review and get them to Mike who will send them to OAR.

Thanks for working on a holiday weekend --

Kelly

Ex. 6 Personal Privacy (PP) all anytime

From: Wilson, Holly [Wilson.Holly@epa.gov]

Sent: 5/24/2019 11:03:14 PM

To: jdurocher@indianheadpark-IL.gov; Walts, Alan [walts.alan@epa.gov]; Mckelvey, Laura [Mckelvey.Laura@epa.gov];

Douglas Pollock [DPOLLOCK@BURR-RIDGE.GOV]; sbucha3@uic.edu; Village Administrator [villageadmin@willowbrook.il.us]; Shappley, Ned [Shappley.Ned@epa.gov]; Dunn, Matthew

[MDunn@atg.state.il.us]; mna9@cdc.gov; Nam, Ed [nam.ed@epa.gov]; kim.biggs@illinois.gov; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Terry, Sara [Terry.Sara@epa.gov]; Bremer,

Kristen [Bremer.Kristen@epa.gov]; Srikant Rao [mslrao71@gmail.com]; Dennis Brennan

[Dennis.Brennan@dupagehealth.org]; Margaret Donnell [Margaret.Donnell@HISCOX.com]; Rimer, Kelly

[Rimer.Kelly@epa.gov]; Urszula Tanouye [urszula.tanouye@gmail.com]; Victor Simon [vsimon@gower62.com]; Evan Walter [EWalter@burr-ridge.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Dr. Tiefu Shen: [tiefu.shen@illinois.gov]; Kyle.Garner@Illinois.gov; Roche, Laura [Laura.Roche@Illinois.Gov]; Frost, Brad [Brad.Frost@Illinois.gov]; Cuculich,

Thomas [Thomas.Cuculich@dupageco.org]; Kristi Celico [kcelico@gmail.com]; Prentiss,Tamara

[tprentis@hinsdale86.org]; Karen J. Ayala [kayala@dupagehealth.org]; Ward, Hillary [Ward.Hillary@epa.gov]; Beckmann, Ronna Erin [beckmann.ronna@epa.gov]; Gayle Neal [gneal@willowbrook.il.us]; mkj5@cdc.gov; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Kottmeyer, Nick [Nick.Kottmeyer@dupageco.org]; Bendinelli, Angela [ABendinelli@dupageco.org]; Sieffert, Margaret [Sieffert.Margaret@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Furey, Eileen [furey.eileen@epa.gov]; Kelley, Jeff [kelley.jeff@epa.gov]; Singer, Joshua [Singer.Joshua@epa.gov];

Siegel, Kathryn [siegel.kathryn@epa.gov]; Hart, Greg [Greg.Hart@dupageco.org]; Hinz, Joy [Joy.Hinz@dupageco.org]; Renehan, Julie [Julie.Renehan@dupageco.org]; Cutrona, Jennifer L

[jennifer.cutrona@gdit.com]; Cobb, Rick [rick.cobb@illinois.gov]; jdurocher@indianheadpark-IL.gov; Douglas Pollock [DPOLLOCK@BURR-RIDGE.GOV]; sbucha3@uic.edu; Village Administrator [villageadmin@willowbrook.il.us]; Dunn, Matthew [MDunn@atg.state.il.us]; mna9@cdc.gov; kim.biggs@illinois.gov; Srikant Rao [mslrao71@gmail.com];

Dennis Brennan [Dennis.Brennan@dupagehealth.org]; Margaret Donnell [Margaret.Donnell@HISCOX.com]; Urszula Tanouye [urszula.tanouye@gmail.com]; Victor Simon [vsimon@gower62.com]; Evan Walter [EWalter@burr-

ridge.gov]; Dr. Tiefu Shen: [tiefu.shen@illinois.gov]; Kyle.Garner@Illinois.gov; Roche, Laura

[Laura.Roche@Illinois.Gov]; Frost, Brad [Brad.Frost@Illinois.gov]; Cuculich, Thomas

[Thomas.Cuculich@dupageco.org]; Kristi Celico [kcelico@gmail.com]; Prentiss,Tamara [tprentis@hinsdale86.org];

Karen J. Ayala [kayala@dupagehealth.org]; Gayle Neal [gneal@willowbrook.il.us]; Kottmeyer, Nick [Nick.Kottmeyer@dupageco.org]; Bendinelli, Angela [ABendinelli@dupageco.org]; Hart, Greg

[Greg.Hart@dupageco.org]; Hinz, Joy [Joy.Hinz@dupageco.org]; Renehan, Julie [Julie.Renehan@dupageco.org];

Cutrona, Jennifer L [jennifer.cutrona@gdit.com]; Cobb, Rick [rick.cobb@illinois.gov]

CC: Orris, Peter [porris@uic.edu]; Smith, Lisa [Lisa.Smith@dupageco.org]

Subject: Public Meeting on Ethylene Oxide, May 29 2019

Attachments: 5.29 Willowbrook Meeting Draft Agenda FINAL.docx; May 29 Open House Resource Tables FINAL.docx

Final agenda and list of open house resource tables.

See you next week and have a great holiday weekend

Cheers,

Holly Wilson Outreach and Information Division Office of Air Quality Planning| and Standards Environmental Protection Agency MD: C304-03, RM: C-305K Research Triangle Park, NC 27711 (919)541-5624 wilson.holly@epa.gov

# Public Meeting on Ethylene Oxide

May 29, 2019, 6:00 PM - 10:00 PM

# Chicago Marriott Southwest at Burr Ridge - Ballroom

1200 Burr Ridge Parkway, Burr Ridge, IL 60527

Remote participants can join by visiting [HYPERLINK "https://www.facebook.com/pg/brvillage/events/"] and clicking **EPA Meeting May 29**.

#### 6:00 PM MEETING START

Facilitators will call the meeting to order and review the approach and agenda.

#### 6:10 PM WELCOME

Agency and Local Officials will discuss their goals and expectations for the meeting.

- USEPA Region 5 Administrator Cathy Stepp
- USEPA Assistant Administrator for the Office of Air and Radiation Bill Wehrum
- Burr Ridge Mayor Gary Grasso
- Willowbrook Mayor Frank Trilla
- Stop Sterigenics Margaret Donnell & Neringa Zymancius
- Illinois Department of Public Health Acting Director Dr. Ngozi Ezike
- Illinois EPA Acting Director John Kim

## 6:30 PM PRESENTATIONS ON CURRENT STUDIES AND REPORTS

Agency staff will provide updates and results from recent health and environmental studies on the Willowbrook Sterigenics facility.

- Overview of Current Information -- Mike Koerber, USEPA
- IEPA Well Water Sampling Brad Frost, IEPA
- EPA Risk Assessment--Kelly Rimer, USEPA
- Update on ATSDR follow up Health Consultation Mark Johnson and Michelle Colledge, ATSDR
- IDPH Cancer Study— Kyle Garner and Dr. Tiefu Shen, IDPH

## 7:40 PM STAKEHOLDER Q&A PANEL ON THE STUDIES AND REPORTS

Stakeholder panel will ask questions related to the current reports that are most important to the community, including questions gathered at the Open House.

- Richard Morton EtO Medical Monitoring
- Greg Hart DuPage County Board Member
- Urszula Tanouye Stop Sterigenics
- Dr. Susan Buchanan University of Illinois-Chicago

### 8:40 PM NEXT STEPS

- EPA: EPA National Rule For Commercial Sterilizers Bill Wehrum
- IEPA: Next Steps on Sterigenics Willowbrook John Kim

### 9:00 PM STAKEHOLDER O&A PANEL ON NEXT STEPS

Stakeholder panel will ask questions related to next steps that are most important to the community, including questions gathered at the Open House.

- Margaret Donnell Citizens for Clean Air, NFP
- Srikant Rao Stop Sterigenics
- Neringa Zymancius Stop Sterigenics
- Julie Renehan DuPage County Board Member

# 9:50 PM WRAP-UP

Facilitators will review any key outcomes from the meeting and ongoing additional opportunities for public input.

10:00 PM ADJOURN

# Open House

May 29, 2019, 2:00 PM – 5:00 PM Chicago Marriott Southwest at Burr Ridge 1200 Burr Ridge Parkway, Burr Ridge, IL 60527

Gallery 1/2/3/4/

Speakers	Organization	Topic Area
Kelly Rimer Darcie Smith	US Environmental Protection Agency (USEPA)	PPA's Risk Assessment of Sterigenics Facility: National Air Toxics Assessment (NATA) - Risk assessor(s) with the U.S. EPA's Office of Air and Radiation will be on hand to discuss the results of the risk assessment conducted for the Sterigenics facility in Willowbrook, IL.
Michelle Colledge Mark Johnson	Agency for Toxic Substances and Disease Registry (ATSDR)	Public Health & EtO - ATSDR follow up Health Consultation
Dr. Tiefu Shen Kyle Garner	Illinois Department of Public Health (IDPH)	IDPH Cancer Study - Dr. Tiefu Shen is the Chief of the Division of Epidemiological Studies and Mr. Kyle Garner is a cancer epidemiologist, both within the Illinois Department of Public Health. Together Dr. Shen and Mr. Garner represent 32 years of experience and knowledge working with the Illinois State Cancer Registry, the only source for high quality, population-based cancer incidence information in Illinois.
Emily Szwiec Dr. Aditi Vyas Dr. Susan Buchanan	Region 5 Pediatric Environmental Health Specialty Unit / Great Lakes Center for Children's Environmental Health Chicago Chapter of Physicians for Social Responsibility	Pediatric Health Issues - The PEHSU will provide expertise on the health effects of EtO and other environmental exposures. We will also provide resources for people on environmental health concerns in their community.  [ HYPERLINK "http://publichealth.uic.edu/great-lakes/childrens-health" ]
Lew Weinstock Ned Shappley Michael Compher Jackie Nwia	USEPA USEPA USEPA Region 5 USEPA Region 5	Source Measurement and Ambient Monitoring - This table will be staffed by EPA personnel who have worked on both the source testing of the Sterigenics facilities as well as the ambient monitoring study that was conducted between November 2018 and March 2019.
Jan Cortelyou-Lee Kristen Bremer	USEPA USEPA	<b>Got Questions? –</b> Submit questions for the public meeting.
Laura Mckelvey Sara Terry Katie Siegel	USEPA USEPA USEPA Region 5	Let's Talk – Open Discussion

	:	
Holly Wilson Alexis Cain Margaret Sieffert	USEPA USEPA Region 5 US EPA Region 5	Outreach and Information - Resource Materials (Facts sheets, Websites, Handouts, CAA, Timelines etc.) Sign up for email notifications on future engagement opportunities (i.e webinars, monitoring data, regulatory updates, etc.) General knowledge of air toxics, EtO, Sterigenics, monitoring.
Brad Frost Elizabeth Wallace Daniel Rottenberg	Illinois EPA Illinois Attorney General Illinois Attorney General	State Environmental and Regulatory
	Community	Tables
Neringa Zymancius Margie Donnell	Stop Sterigenics Group	Community Grassroots Activities
Richard Morton Ivette Collins Jeanne Hochhalter Kelly Kishel Yvonne Mayer Cathleen O'Hare	EtO Medical Monitoring	Concerned Citizens/Monitoring - Concerned about the challenges facing our community past, present and future from the 35 years of EXPOSURE to ETHYLENE OXIDE. EtO Medical Monitoring is working on establishing a medical monitoring program adequately funded and supported by legislation.
Trustee Guy Franzese Evan Walter	Burr Ridge Environmental Quality Commission	Village Advisory Board
Michael Mertens Trustee Gayle Neal	Village of Willowbrook Environmental Task Force	Village Advisory Board -The Willowbrook Environmental Task Force has been formed with the specific responsibility and authority to recommend immediate and long-term actions for the health and safety of our area residents, employees and business owners. The Task Force consists of qualified independent professionals that will study, assess, interpret, evaluate risk, and then recommend the necessary actions to be taken in response to the findings indicated on the ATSDR report of August 21, 2018.
Catherine and Alexandra Collins	Students Against EtO	<b>Hinsdale Central High School: Student Educational Advocacy -</b> Students working to inform their peers and community of the increased dangers ethylene oxide presents to the community to younger demographics.
	i Industry T	able
	Sterigenics (Invited)	

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 5/29/2019 1:05:02 PM

**To**: Bremer, Kristen [Bremer.Kristen@epa.gov]

Subject: Can you work from this draft? Risk Assessment Results for Sterigenics - Willowbrook V6 FINAL.pptx

Attachments: Risk Assessment Results for Sterigenics - Willowbrook V6 FINAL.pptx

I made some changes to speaker notes

From: Mckelvey, Laura [Mckelvey.Laura@epa.gov]

**Sent**: 4/11/2019 8:03:44 PM

To: EtO [EtO@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Davis,

Alison [Davis.Alison@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]; Gmyr, Joanna [Gmyr.Joanna@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Terry, Sara [Terry.Sara@epa.gov];

Strum, Madeleine [Strum.Madeleine@epa.gov]; Witt, Jon [Witt.Jon@epa.gov]; Caparoso, Jennifer

[Caparoso.Jennifer@epa.gov]; Shappley, Ned [Shappley.Ned@epa.gov]

Subject: FW: Illinois State Medical Statement

Attachments: LateResolutionA.pdf

#### **Thanks**

From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com>

Sent: Thursday, April 11, 2019 2:24 PM

To: Mckelvey, Laura < Mckelvey.Laura@epa.gov>; Koerber, Mike < Koerber.Mike@epa.gov>

Subject: Illinois State Medical Statement

Just passing this along

## ILLINOIS STATE MEDICAL SOCIETY

Late Resolution A (A-19)

Introduced by: Peter Orris, M.D., M.P.H., Aditi Vyas, M.D., M.P.H. and A. Jay

Chauhan, D.O., ISMS Members

Subject: Removing Ethylene Oxide as a Medical Sterilant from Healthcare

Whereas, on February 15, 2019, at 10:30 PM Michael Hawthorne in the Chicago Tribune reported that "Gov. J.B. Pritzker's administration on Friday banned <u>Sterigenics from using ethylene oxide</u> at its Willowbrook sterilization plant, responding to an intense public outcry about toxic air pollution that left surrounding neighborhoods with some of the highest cancer risks in the nation." Yet no action was taken with respect to facilities in the Waukegan and Gurnee areas nor attention given to assuring the necessary sterile medical supplies; and

Whereas, ethylene oxide is a known human carcinogen as identified by the International Agency for Research on Cancer (IARC) and USEPA. It is used for sterilization of medical equipment that cannot be sterilized by steam. This process is open to the workplace environment at various points allowing the escape of EtO into the area and community. Safer substitution, therefore, should be considered, as alternatives exist that are equally efficacious with respect to sterilization of non-metal products. [6] While many hospitals have switched away from ethylene oxide due to the toxicities, an estimated 80% of non-metallic medical equipment is still being sterilized with EtO at industrial facilities before delivery [6]; and

Whereas, only 0.05% of the annual production is used for sterilization, sterilization and fumigation is where the highest exposure levels to workers and communities have been measured. [6] Inhaling contaminated air exposes surrounding communities to ethylene oxide when the gas is released from a sterilant facility; and

Whereas, ethylene oxide exposure is associated with irritation of the respiratory tract, eyes, and skin. [6] With direct contact it can cause burns, blistering, and desquamation of the skin. It can also cause conjunctivitis and contact dermatitis. [6, 4] Acute high-level exposure can cause asthma, and sensitization. [6, 4] It can lead to peripheral neuropathy and central neurotoxicity including neuropsychological abnormalities, and seizures. [4] In animals, exposure has been shown to cause spontaneous abortion, preterm births, and reproductive toxicity in both males and females [4][6]; and

Whereas, in 1984, the International Agency for Research on Cancer (IARC) included ethylene oxide in its list as a probable carcinogen by 2008 with adequate information available only in animals, microorganisms, and invitro. It has been shown to induce sensitive, persistent dose-related frequency of chromosomal aberrations, sister chromatid exchange in peripheral lymphocytes and micronuclei in bone-marrow cells of exposed workers [4][14]; and

Whereas, epidemiologic studies of humans in 2004, since reviewed by IARC and USEPA, have documented EtO as a Class 1 known human carcinogen. EtO's carcinogenic impact is due to its action as an alkylating agent and specifically has been associated with malignancies of the breast, lymphatic and hematopoietic systems in humans [6][18][19]; and

Whereas, based on this new information, USEPA changed EtO's adult-based inhalation unit risk from 0.0001 per microgram per cubic meter ( $\mu g/m^3$ ) to 0.003 per  $\mu g/m^3$ , a 30-fold increase in cancer potency. In Willowbrook, Illinois, this elevated the additional lifetime risk of 6.4 cancers in a population of 1,000 residents who could be exposed to EtO emissions from a local industrial sterilizing facility. This cancer risk exceeds U.S. EPA's decision-making cancer risk range of 1.0 x 10-6 to 1.0 x  $10^{-4}$ , and adds to the lifetime background cancer risk of an average American of 1 in 3 people [24] [25]; and

Whereas, for community exposures no regulations exist save the USEPA's advice with respect to carcinogenic risk and the need for action when the risk exceeds the U.S. EPA's decision-making cancer risk range of 1.0 x 10-6 to 1.0 x 10-4; and

Whereas, due to the impossibility of sterilizing these materials in an enclosed system, safer substitution is the most effective means to address this problem of EtO community exposures. As described by the industry consensus standards Association for the Advancement of Medical Instrumentation, these include radiation sterilization, hydrogen peroxide, nitrogen dioxide and hydrogen peroxide-ozone. The Federal Drug Administration noted in 2016 that hydrogen peroxide was an alternative that they were familiar with and invited applications for sterilization process reviews using this chemical [23]; and

Whereas, on February 19, 2019, the Chicago Medical Society adopted policy that supports the substitution of ethylene oxide with less toxic alternatives that are currently available, including hydrogen peroxide, steam, and other safer alternatives, which do not release carcinogens into the workplace or community and allow no residual exposures to the patient; the new policy directs CMS to urge the prevention of emissions or the phase-out of EtO and replacement with other safer methods of sterilization in health care; CMS policy also states that when health care facilities are evaluating

surgical and medical devices that require sterilization, in addition to effectiveness of the device for best patient outcomes, that the facilities also be required to prioritize the modes of sterilization for the highest degree of worker and environmental safety; therefore, be it

RESOLVED, that the Illinois State Medical Society (ISMS) adopt as policy and urge, as appropriate, the substitution of ethylene oxide with less toxic alternatives that are currently available, including hydrogen peroxide, steam, and other safer alternatives, which do not release carcinogens into the workplace or community air and allow no residual exposures to the patient, and that ISMS urge the prevention of emissions or the phase-out of EtO and replacement with other safer methods of sterilization in health care; and be it further

RESOLVED, that ISMS adopt as policy and urge that when health care facilities are evaluating surgical and medical devices that require sterilization, in addition to effectiveness of the device for best patient outcomes, that facilities also be required to prioritize the modes of sterilization for the highest degree of worker and environmental safety; and be it further

RESOLVED, that ISMS bring this resolution to the American Medical Association (AMA) for adoption as policy and to urge, as appropriate, the substitution of ethylene oxide with less toxic alternatives that are currently available, including hydrogen peroxide, steam, and other safer alternatives, which do not release carcinogens into the workplace or community air and allow no residual exposures to the patient, and that AMA urge the prevention of emissions or the phase-out of EtO and replacement with other safer methods of sterilization in health care; and be it further

RESOLVED, that ISMS request that AMA adopt as policy and urge that when health care facilities are evaluating surgical and medical devices that require sterilization, in addition to effectiveness of the device for best patient outcomes, that facilities also be required to prioritize the modes of sterilization for the highest degree of worker and environmental safety.

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Ethylene oxide (EtO) is a chemical used to sterilize medical equipment in hospitals, healthcare facilities, and industrial settings. It is also used to fumigate items that cannot be sterilized by steam such as spices, cosmetics, and plastic devices. While over 95 percent of industrial use of EtO is for closed reaction to less volatile, explosive, and toxic derivatives such as ethylene glycol, 0.5% is used in sterilizing processes designed to kill bacterial and other living organisms. It is estimated that over 80% of medical supplies in the US composed of rubber or plastic are sterilized in this manner. Workers,

including those in health care, engaged in these activities and the surrounding communities are exposed on a regular basis.

The World Health Organization's International Agency for Research on Cancer (IARC) concluded in 2008 that ethylene oxide is a known human carcinogen. Data has shown that ETO causes lymphopoietic and breast cancers, reproductive toxicity, central and peripheral neurologic damage, and sensitization. In 2016, the US Environmental Protection Agency, after 4 years and 2 external peer reviews, recognized ETO as a known carcinogen and readjusted its toxicity estimate. The FDA recognizes alternatives which are less toxic to accomplish the same sterilization tasks including but not limited to Hydrogen Peroxide. While not compromising patient care, the orderly substation of less hazardous substances is recommended and the immediate control of releases utilizing best available technologies.

# **Fiscal Note:**

N/A

# **Existing ISMS policy related to this issue:**

ISMS fully supports patient safety initiatives and quality measures designed to improve medical outcomes. (HOD 2011; BOT 2012-FEB; Last BOT Review 2012)

ISMS encourages the development of national environmental contaminant biomonitoring programs to track harmful chemicals and toxic agents. (HOD 2007; Last BOT Review 2014)

ISMS encourages health care professionals to frequently clean their stethoscopes and handheld devices between patient encounters, and urges that all locations where physicians practice have the appropriate cleaner or disposable options accessible for use to minimize the potential risk of nosocomial infection. (HOD 2015)

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 5/24/2019 1:01:43 PM

**To**: Bremer, Kristen [Bremer.Kristen@epa.gov]

Subject:Risk Assessment Results for Sterigenics- Willowbrook v1.pptxAttachments:Risk Assessment Results for Sterigencs- Willowbrook v1.pptx

Hi,

Thanks for using your artistic skills to present the graphics!

Kelly

From: Koerber, Mike [Koerber.Mike@epa.gov]

**Sent**: 5/28/2019 8:51:20 PM

To: Bremer, Kristen [Bremer.Kristen@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Rimer, Kelly

[Rimer.Kelly@epa.gov]

**Subject**: Fwd: Risk assessment summary to share with Clint

Attachments: Sterigenics risk assessment summary v5.short version io.docx; ATT00001.htm

# Sent from my iPhone

Begin forwarded message:

From: "Woods, Clint" < woods.clint@epa.gov > To: "Koerber, Mike" < Koerber.Mike@epa.gov > Cc: "Lewis, Josh" < Lewis.Josh@epa.gov >

Subject: RE: Risk assessment summary to share with Clint

----Original Message----

From: Woods, Clint

Sent: Tuesday, May 28, 2019 3:45 PM

To: Koerber, Mike < Koerber. Mike@epa.gov >

Cc: Lewis, Josh < <u>Lewis.Josh@epa.gov</u>>

Subject: RE: Risk assessment summary to share with Clint

That would be great - 202.564.6562

----Original Message-----From: Koerber, Mike

Sent: Tuesday, May 28, 2019 3:43 PM To: Woods, Clint < woods.clint@epa.gov>

Cc: Lewis, Josh < Lewis. Josh@epa.gov>

Subject: Re: Risk assessment summary to share with Clint

Yes! Want us to call you?

Sent from my iPhone

On May 28, 2019, at 3:19 PM, Woods, Clint < woods.clint@epa.gov > wrote:

Mike,

We have a few small edits to each of the docs - Would you all have 10 mins to run through?

On May 27, 2019, at 3:12 PM, Koerber, Mike < Koerber.Mike@epa.gov > wrote:

Comments? Per Alison's note, we'd like to post and distribute by Wednesday morning.

Sent from my iPhone

Begin forwarded message:

From: "Davis, Alison"

<Davis.Alison@epa.gov<mailto:Davis.Alison@epa.gov>>

To: "Koerber, Mike"

< Koerber.Mike@epa.gov < mailto:Koerber.Mike@epa.gov >>>

Subject: Risk assessment summary to share with Clint

Reflects Darcie's edit and one Kelly just requested.

We would hand this out at the open house, and post it to the Web – either late Tuesday or first thing Wednesday morning. We

<Sterigenics risk assessment summary v5.short version. .docx>

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 5/28/2019 7:45:35 PM

**To**: Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: Risk Assessment Results for Sterigenics - 5 28 19 afternoon slides.pptx **Attachments**: Risk Assessment Results for Sterigenics - 5 28 19 afternoon slides.pptx

From: Koerber, Mike [Koerber.Mike@epa.gov]

**Sent**: 8/19/2019 12:55:32 PM

To: Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Terry, Sara [Terry.Sara@epa.gov]; Long, Pam [Long.Pam@epa.gov];

Shappley, Ned [Shappley.Ned@epa.gov]; Weinstock, Lewis [Weinstock.Lewis@epa.gov]; Bremer, Kristen

[Bremer.Kristen@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Cortelyou-Lee, Jan [Cortelyou-Lee.Jan@epa.gov]; Wilson, Holly [Wilson.Holly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]; Davis, Alison [Davis.Alison@epa.gov];

EtO [EtO@epa.gov]

**Subject**: RE: Link to risk assessment report for Sterigenics Willowbrook

This is addressed in the report.

From: Mckelvey, Laura < Mckelvey. Laura@epa.gov>

Sent: Monday, August 19, 2019 8:49 AM

**To:** Terry, Sara <Terry.Sara@epa.gov>; Long, Pam <Long.Pam@epa.gov>; Shappley, Ned <Shappley.Ned@epa.gov>; Koerber, Mike <Koerber.Mike@epa.gov>; Weinstock, Lewis <Weinstock.Lewis@epa.gov>; Bremer, Kristen <Bremer.Kristen@epa.gov>; Rimer, Kelly <Rimer.Kelly@epa.gov>; Cortelyou-Lee, Jan <Cortelyou-Lee.Jan@epa.gov>;

Wilson, Holly <Wilson.Holly@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>; Davis, Alison <Davis.Alison@epa.gov>;

EtO <EtO@epa.gov>

Subject: Fwd: Link to risk assessment report for Sterigenics Willowbrook

Need to look at this chain

Sent from my iPhone

Begin forwarded message:

From: Mark Winters Ex. 6 Personal Privacy (PP) DSbcglobal.net>

Date: August 19, 2019 at 8:17:13 AM EDT

To: "Mckelvey, Laura" < Mckelvey.Laura@epa.gov>

Cc: john.j.kim@illinois.gov

Subject: Re: Link to risk assessment report for Sterigenics Willowbrook

My only question is why is IL EPA using 85 lbs when this risk assessment is using way less.

TOTALLY UNACCEPTABLE !!!

IMHO Violates IL Constitution John Kim !!!!

Sent from my iPhone

On Aug 15, 2019, at 4:03 PM, Mckelvey, Laura < Mckelvey. Laura@epa.gov> wrote:

Hi folks,

I wanted to make sure y'all saw this. Let me know if you have questions.

Thanks

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 8/13/2019 4:44:03 PM

**To**: Bremer, Kristen [Bremer.Kristen@epa.gov]

Subject: Blurb

Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois

This report documents in detail the steps taken to estimate risk from ethylene oxide emissions from the Sterigenics facility in Willowbrook, III. The conclusions in the report were presented a public meeting in Burr Ridge, Illinois on May 29, 2019.

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 5/30/2019 12:10:21 AM

To: Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: USE THESE INSTEAD -- FW: presentations for posting

Attachments: US EPA Overview of Current Information.5.29.19.pdf; EPA National Rule for Commercial Sterilizers.5.29.19.pdf; Risk

Assessment Results for Sterigenics - Willowbrook.5.29.19.pdf

Importance: High

Had to replace Kelly's. These files should be right.

From: Davis, Alison

**Sent:** Wednesday, May 29, 2019 8:04 PM **To:** Bremer, Kristen < Bremer.Kristen@epa.gov>

Subject: presentations for posting

Bill's is included but let's see whether he uses them first. His is the national rule.

Maybe something like this for the blurb? Edit as needed – the last bullet would need to come out if Bill doesn't use slides:

# May 29, 2019

U.S. EPA presentations at May 29, 2019 public meeting:

- Overview of current information
- Risk assessment results
- EPA's upcoming national rule for commercial sterilizers

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 5/29/2019 4:25:07 PM

To: Newton, Cheryl [Newton.Cheryl@epa.gov]; Nam, Ed [nam.ed@epa.gov]; Sieffert, Margaret

[Sieffert.Margaret@epa.gov]; Compher, Michael [compher.michael@epa.gov]; Nwia, Jacqueline

[nwia.jacqueline@epa.gov]; Cain, Alexis [cain.alexis@epa.gov]; Siegel, Kathryn [siegel.kathryn@epa.gov]

CC: Koerber, Mike [Koerber.Mike@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]; Shappley, Ned

[Shappley.Ned@epa.gov]; Bremer, Kristen [Bremer.Kristen@epa.gov]

**Subject**: Risk Assessment Results for Sterigenics - Willowbrook V7 FINAL.pptx **Attachments**: Risk Assessment Results for Sterigenics - Willowbrook V7 FINAL.pptx

From: Bremer, Kristen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7AD6F4A11064EF08CB03AEC9DC8E892-KBREMER]

**Sent**: 5/29/2019 3:18:09 PM

To: Koerber, Mike [Koerber.Mike@epa.gov]

**Subject**: Residential Maps

Attachments: Risk Assessment Results MAPS.pptx

I included both residential maps and (zoomed out and in). Feel free to delete one or the other.

Kristen Bremer

Policy Analysis & Communications

U.S. EPA, Office of Air Quality Planning & Standards

Email: <u>bremer.kristen@epa.gov</u>

Phone: 919.541.9424 Cell: 919.321.7652

From: Woods, Clint [woods.clint@epa.gov]

**Sent**: 7/24/2019 2:28:47 PM

To: Koerber, Mike [Koerber.Mike@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]

**Subject**: Willowbrook Assessment

Attachments: RA rpt for Sterigenics Willowbrook IL OAR Review Draft 07 12 19 io.docx

Comments attached – Thanks!

Clint Woods Deputy Assistant Administrator Office of Air and Radiation, U.S. EPA 202.564.6562

From: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Sent**: 6/25/2019 8:03:45 PM

To: Koerber, Mike [Koerber.Mike@epa.gov]; Davis, Alison [Davis.Alison@epa.gov]
CC: Morris, Mark [Morris.Mark@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

Subject: RA rpt for Sterigenics Willowbrook IL.docx
Attachments: RA rpt for Sterigenics Willowbrook IL.docx

Hi,

Here is the draft risk assessment re: the Sterigenics facility for your review. We can send along the appendices if you'd like.

Thanks,

Kelly

### Appointment

From: Dyron.Hamlin@ghd.com [Dyron.Hamlin@ghd.com]

**Sent**: 12/17/2018 8:29:24 PM

**To**: Koerber, Mike [Koerber.Mike@epa.gov]

CC: Cipriano, Renee [RCipriano@schiffhardin.com]; Benjamin.Chandler@ghd.com; Tim Halik [thalik@willowbrook.il.us];

Gayle Neal [gneal@willowbrook.il.us]; 'Lucy Fraiser' [lucy@lucyfraiser-toxicology.com]

Subject: Accepted: Discuss QA Issues

Location: Phone Number Ex. 6 Personal Privacy (PP) Ode= Ex. 6 Personal Privacy (PP)

**Start**: 12/18/2018 3:00:00 PM **End**: 12/18/2018 4:00:00 PM

Show Time As: Busy

Recurrence: (none)

Mike,

We will be on the call tomorrow to compare notes on laboratory analytical methods, results comparison between USEPA and Willowbrook, etc. We have not identified any QA issues in doing our due diligence thus far.

We've reviewed your questions, and we're certainly familiar with canisters and how they work, including pressures, etc. To cover that set of questions at the end of the report, I'll just say in short that our samples were received within appropriate pressure limits, as measured at the lab, and not on the field gauges, which is what we listed in the report, just to ensure as well as we could with field gauges that the samples did not go to ambient pressure.

In short, we're confident in the results, and the sampling procedure, which is fairly simple; we reviewed, and had our project chemist review, the results prior to publishing our report. We haven't seen any interference from compounds biasing our results high; in fact, our result at our single sample co-located with USEPA was slightly lower than the result measured by USEPA (0.576 compared to  $0.824 \,\mu\text{g/m}^3$ , respectively), although within measurement accuracy range (our reported accuracy is 24.7%). Our results did not specifically target trans-2-butene, as we've not identified it specifically as a potential issue; but given the interest raised by the USEPA, the lab is going to look for it and rule it out going forward.

We are also following up in this reply with the following questions and discussion points:

- 1. You mentioned for the results you've received thus far that trans-2-butene was a non-detect at all your sample locations over multiple days. Given that, do you still think your May results are skewed high and if so why?
- 2. Can you explain the increase in measured concentrations from Nov 16 to Nov 19 at the EPA warehouse and Village Hall? We know it is just one data set, but do you think there was a lab error, or is there possibly another explanation?
- 3. What was the sample quantitation limit (SQL) actually achieved during these specific sampling events?
- 4. You noted that samples not meeting identification acceptance criteria would be flagged "ND."
- a. According to the sampling plan, samples below the MDL were supposed to be flagged with "MD". Is this related to identification criteria, rather than method detection limit? I.e., was the presence of a compound identified, but determined not to be EO?

- b. I believe we've asked for chromatograms previously, and have yet to receive them. If you could provide, them, it may be helpful to our laboratory to compare notes.
- 5. Did you evaluate the meteorology conditions on your sampling days (i.e., wind direction and speed, etc.)?
- 6. What issue caused the Nov. 13 results to be invalid?
- 7. EPA's sampling plan states that EPA will work with Sterigenics to make production and EtO usage data available for correlation with ambient results. Does EPA have any information on what the Sterigenics operating conditions were on Nov. 13, 16, and 19?
- 8. Was there a reason EPA didn't deploy at the planned 8 sample locations on November 16, when we had a chance to co-locate numerous additional samples, and were only able to co-locate one?
- 9. Do you have any comments specific to the indoor/outdoor sample result differences? This is a key input to your risk assessment assumption that inside is equal to outside may not be valid.

Those are a few thoughts to guide our discussion tomorrow.
Thanks!
Dyron

CONFIDENTIALITY NOTICE: This email, including any attachments, is confidential and may be privileged. If you are not the intended recipient please notify the sender immediately, and please delete it; you should not copy it or use it for any purpose or disclose its contents to any other person. GHD and its affiliates reserve the right to monitor and modify all email communications through their networks.

Message Koerber, Mike [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C513901D4FD49F9AB101A6F7A7A863E-KOERBER, MIKE] Sent: 8/13/2019 4:51:28 PM Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com] To: Subject: RE: report? Yes, thank you: 919-541-5557 From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com> Sent: Tuesday, August 13, 2019 12:50 PM To: Koerber, Mike < Koerber. Mike@epa.gov> Subject: Re: report? That works. Can I call you? I am in a training and it would be easier if I made the call. Can you send my your number? **Thanks** On Tue, Aug 13, 2019 at 11:05 AM Koerber, Mike < Koerber.Mike@epa.gov > wrote: How about this afternoon? 1:00 pm CDT? If that works, then what number should I call? Thanks. Mike From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com> Sent: Monday, August 12, 2019 8:10 PM To: Koerber, Mike < Koerber. Mike@epa.gov> Subject: Re: report? That would be great. What time works for you? I can be available most of the day. On Mon, Aug 12, 2019 at 6:25 PM Koerber, Mike < Koerber. Mike@epa.gov > wrote: If you're available on Tuesday, then I can call with an update. Thanks. Sent from my iPhone On Aug 12, 2019, at 6:10 PM, Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com> wrote:

Hello again...

would also like to know where the EPA is at with the EtO regulatory process? We have another court date for 9/6. The local villages impacted by Sterigenics have the ability to file a brief outlining their opposition to the recent consent order approved by the state of Illinois. The completed risk assessment information is critical for our villages to have. I appreciate your response and specific timeframe for requests made above. Jen On Mon, Jul 15, 2019 at 8:34 PM Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com > wrote: Hi all-The ILEPA has set the public comment meeting for 8/1. It is imperative that we have all the data, and the full write up from the risk assessment for this meeting. Mike- on 7/5 you indicated that you would be back in touch with me early last week. I am still waiting to hear from you. Perhaps a "call to action" is in order? Do we need to pressure Wheeler and the new Air chief? When can we expect our information?! Jen McConahy On Fri, Jul 5, 2019 at 10:37 AM Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com > wrote: Thanks Mike-It's hard to understand how everyone else in the workplace has to meet our deadlines- and if we don't there are consequences. This is over a month past when it was due to the public. This is very disappointing. Jen On Fri, Jul 5, 2019 at 10:28 AM Koerber, Mike <Koerber.Mike@epa.gov> wrote:

I am once again reaching out to this group to find out where the completed risk assessment is? I

Jen: I talked with Kelly the other day and I think we're closer. I should have a better idea by early next week when more folks are back in the office. I'll be in touch then. Mike From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com> **Sent:** Friday, July 05, 2019 11:19 AM **To:** Koerber, Mike < Koerber. Mike@epa.gov> Cc: Davis, Alison <a href="mailto:Alison@epa.gov">Davis.Alison@epa.gov</a>; Mckelvey, Laura <a href="mailto:Mckelvey.Laura@epa.gov">Mckelvey.Laura@epa.gov</a>; Rimer, Kelly < Rimer. Kelly@epa.gov> Subject: Re: report? Thanks Mike! Hope you had a nice Fourth. Just checking to see if you were able to determine a date for the risk assessment. Jen On Fri, Jun 28, 2019 at 10:40 AM Koerber, Mike <Koerber.Mike@epa.gov> wrote: Jen: Okay, I'll talk with the team here and will be back in touch once we have a better date. Mike From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com> **Sent:** Friday, June 28, 2019 11:34 AM To: Koerber, Mike < Koerber. Mike@epa.gov> Cc: Davis, Alison < Davis. Alison@epa.gov >; Mckelvey, Laura < Mckelvey. Laura@epa.gov >; Rimer, Kelly < Rimer. Kelly@epa.gov> Subject: Re: report? Mike- Can you please provide and estimated time frame? It is critical we have this information as permit commenting will be happening in the near future. Jen On Fri, Jun 28, 2019 at 10:30 AM Koerber, Mike < Koerber. Mike@epa.gov > wrote:

Jen – Thank you for your patience. It has taken us a little longer than expected to finalize the report. We hope to release the report soon. For now, the best we can provide is the summary and slides from the public meeting:

https://www.epa.gov/sites/production/files/2019-05/documents/sterigenics-risk-assessment-summary-05292019.pdf

https://www.epa.gov/il/sterigenics-willowbrook-facility-community-meeting-presentations

Mike

From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com>

**Sent:** Friday, June 28, 2019 11:09 AM

To: Koerber, Mike < Koerber. Mike@epa.gov >; Mckelvey, Laura < Mckelvey. Laura@epa.gov >

Subject: report?

Hi there-

I am wondering when the completed risk assessment will be released? I'm sure you have heard that Sterigenics has applied for a construction permit with the ILEPA. We need this report now so we can accurately plan for our opposition to this permit.

We are now over four weeks out from the community forum and still waiting.

Jen

From: Koerber, Mike [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C513901D4FD49F9AB101A6F7A7A863E-KOERBER, MIKE]

**Sent**: 8/19/2019 3:38:07 PM

To: Jennifer McConahy Ex.6 Personal Privacy (PP) @gmail.com]

CC: Davis, Alison [Davis.Alison@epa.gov]; Margaret Donnell Ex. 6 Personal Privacy (PP) hiscox.com]; Rimer, Kelly

[Rimer.Kelly@epa.gov]

Subject: RE: (EXT) Re: FW: EPA Report

The risk assessment results for the baseline scenario are on pages 24 and 25 of the report. As I indicated previously, although we did not prepare any new maps, we did provide risk levels as a function of distance. So, I believe the information is in the report – just not in graphical form.

Mike

From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com>

**Sent:** Monday, August 19, 2019 10:38 AM **To:** Koerber, Mike < Koerber. Mike@epa.gov>

Cc: Davis, Alison < Davis. Alison@epa.gov>; Margaret Donnell Ex. 6 Personal Privacy (PP) @hiscox.com>; Rimer, Kelly

<Rimer.Kelly@epa.gov>

Subject: Re: (EXT) Re: FW: EPA Report

Hi Mike-

I am checking in to see if you were able to find answers to the questions Margie and I had.

Thanks-Jen

On Wed, Aug 14, 2019 at 6:22 PM Koerber, Mike < Koerber. Mike@epa.gov> wrote:

The report reflects the information presented at the public meeting. Although we did not prepare any new maps, we did provide risk levels as a function of distance in the text of the report. I believe that is responsive to questions we received at the meeting.

Mike

Sent from my iPhone

On Aug 14, 2019, at 6:40 PM, Margaret Donnell Ex. 6 Personal Privacy (PP) @hiscox.com wrote:

I agree with Jen. The new map was supposed to break down the risk beyond the 100 in 1m mark. Can you advise why that was not done and perhaps what the hold up was all these months if we received nothing other than what was provided in May?

Thank you,

Margie Donnell, Esq. Sr. Claims Counsel - Professions Architects & Engineers Direct: 312.283.2917

From: Jennifer McConahy Ex. 6 Personal Privacy (PP) @gmail.com>

**Sent:** Wednesday, August 14, 2019 3:11 PM **To:** "Koerber, Mike" < Koerber. Mike@epa.gov>

CC: Margaret Donnell Ex. 6 Personal Privacy (PP) @HISCOX.com> Subject: (EXT) Re: FW: EPA Report
Thanks Mike-
Upon first glance, the maps were not updated to reflect risk beyond 100-200 cases per million. Why was this not done? I believe we spoke about it at the pre-meeting for the community forum and at the forum and EPA agreed to adjust the map.  Thanks- Jen
On Wed, Aug 14, 2019 at 4:22 PM Koerber, Mike < Koerber.Mike@epa.gov > wrote:
FYI
From: Koerber, Mike Sent: Wednesday, August 14, 2019 5:22 PM To: Doug Pollock <a href="mailto:DPOLLOCK@BURR-RIDGE.GOV">DPOLLOCK@BURR-RIDGE.GOV</a> ; Evan Walter <a href="mailto:EWalter@burr-ridge.gov">EWalter@burr-ridge.gov</a> ; Gayle Neal <a href="mailto:Qneal@willowbrook.il.us">Qneal@willowbrook.il.us</a> ; John Durocher <a href="mailto:jdurocher@indianheadpark-il.gov">jdurocher@indianheadpark-il.gov</a> ; Tom Hinshaw <a href="mailto:thinshaw@indianheadpark-il.gov">Athinshaw@indianheadpark-il.gov</a> ; Victor Simon <a href="mailto:vsimon@gower62.com">vsimon@gower62.com</a> ; Frank Trilla <a href="mailto:ftrilla@willowbrook.il.us">ftrilla@willowbrook.il.us</a> > Subject: EPA Report
Today, we posted the final Risk Assessment Report for the Sterigenics facility in Willowbrook, Illinois. This report documents in detail the steps taken to estimate risk from ethylene oxide emissions from the facility. The conclusions in the report are the same as those presented at a public meeting in Burr Ridge, Illinois on May 29, 2019.
www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il
Please let me know if you have any questions.
Mike
Michael Koerber
Deputy Director

# Office of Air Quality Planning and Standards

(919) 541-5557

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From: Koerber, Mike [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C513901D4FD49F9AB101A6F7A7A863E-KOERBER, MIKE]

**Sent**: 7/24/2019 5:05:53 PM

**To**: Armitage, Julie [Julie.Armitage@Illinois.gov]

**Subject**: Draft Report

Attachments: RA rpt for Sterigenics Willowbrook IL Draft 07 24 19.docx

Julie: Attached please find our draft risk assessment report. I would appreciate any comments from IEPA – in particular, whether you think it would be helpful if we released before the end of the month. Thanks.

Mike

From: Koerber, Mike [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9C513901D4FD49F9AB101A6F7A7A863E-KOERBER, MIKE]

**Sent**: 8/14/2019 9:28:40 PM

To: Armitage, Julie [Julie.Armitage@Illinois.gov]

Subject: FW: EPA Report

Sorry - wrong address. I'm resending.

From: Koerber, Mike

Sent: Wednesday, August 14, 2019 5:26 PM

**To:** Morgan, James < Morgan. James@epa.gov>; Armitage. Julie@Illinois.gov; Mattison. Kevin@Illinois.gov; Eric. E. Jones@Illinois.gov; Lisa. Smith@dupageco.org; Steven. King@Illinois.gov; Gregory. Vaci@dupageco.org; Wallace,

Elizabeth <EWallace@atg.state.il.us>; Wallace, Elizabeth <EWallace@atg.state.il.us>; Dunn, Matthew

<MDunn@atg.state.il.us>; Wells, Christopher <CWells@atg.state.il.us>; Roche, Laura <Laura.Roche@illinois.gov>;

Rottenberg, Daniel < DRottenberg@atg.state.il.us>

Cc: Newton, Cheryl <Newton.Cheryl@epa.gov>; Mooney, John <Mooney.John@epa.gov>; Siegel, Kathryn

<siegel.kathryn@epa.gov>; Rountree, Jillian <Rountree.Jillian@epa.gov>

Subject: FW: EPA Report

FYI

From: Koerber, Mike

Sent: Wednesday, August 14, 2019 5:22 PM

To: Doug Pollock <<u>DPOLLOCK@BURR-RIDGE.GOV</u>>; Evan Walter <<u>EWalter@burr-ridge.gov</u>>; Gayle Neal

<gneal@willowbrook.il.us>; John Durocher <idurocher@indianheadpark-il.gov>; Tom Hinshaw

<thinshaw@indianheadpark-il.gov>; Victor Simon <vsimon@gower62.com>; Frank Trilla <ftrilla@willowbrook.il.us>

Subject: EPA Report

Today, we posted the final Risk Assessment Report for the Sterigenics facility in Willowbrook, Illinois. This report documents in detail the steps taken to estimate risk from ethylene oxide emissions from the facility. The conclusions in the report are the same as those presented at a public meeting in Burr Ridge, Illinois on May 29, 2019.

www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il

Please let me know if you have any questions.

Mike

Michael Koerber Deputy Director Office of Air Quality Planning and Standards (919) 541-5557

From: Smith, Darcie [Smith.Darcie@epa.gov]

**Sent**: 3/21/2019 4:16:34 PM

To: Morris, Mark [Morris.Mark@epa.gov]

**Subject**: just in case - RA report

Attachments: RA rpt for Sterigenics Willowbrook IL.docx

Hi Mark -

I don't think you'll need this and/or the documentation needs could go in an entirely different direction in a week, but just in case... Attached is a draft of the document I started for the risk assessment. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

EX. 5 Deliberative Process (DP) Anyway, I don't think you'll need this next week, but at least you've got it if you do.

Thanks, Darcie

Darcie Smith U.S. EPA/OAQPS/ATAG

919.541.2076

smith.darcie@epa.gov

From: Shappley, Ned [Shappley.Ned@epa.gov]

**Sent**: 7/10/2019 4:46:41 PM

To: Morris, Mark [Morris.Mark@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

CC: Thurman, James [Thurman.James@epa.gov]; Segall, Robin [Segall.Robin@epa.gov]; Johnson, Steffan

[johnson.steffan@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: Risk Assessment Appendix-Emission Estimates

Attachments: Development of EtO emission rates\_willowbrook\_07\_10\_2019(FINAL).docx

# Mark/Darcie,

Sorry for the delay, attached is the Appendix on emission estimates for the Willowbrook Risk Assessment, please let me know if you have any questions.

Thanks,

Ned Shappley | USEPA | OAQPS | AQAD | Measurement Technology Group 109 TW Alexander Drive (E143-02) | Research Triangle Park, NC 27711

email: shappley.ned@epa.gov | Phone (919)541-7903 | Mobile (919)665-9903

From: Smith, Darcie [Smith.Darcie@epa.gov]

**Sent**: 7/10/2019 3:30:09 PM

To: Morris, Mark [Morris.Mark@epa.gov]

Subject: FW: Document review

Attachments: Development of EtO emission rates\_willowbrook\_07\_09\_2019\_jt.docx

Fyi

Darcie Smith
U.S. EPA/OAQPS/ATAG
919.541.2076

smith.darcie@epa.gov

From: Thurman, James

**Sent:** Wednesday, July 10, 2019 10:00 AM **To:** Shappley, Ned <Shappley.Ned@epa.gov> **Cc:** Smith, Darcie <Smith.Darcie@epa.gov>

Subject: RE: Document review

Ned,

Thanks for the opportunity to review. I made a few edits, nothing major I think. Changes are in track changes mode.

**James** 

James A. Thurman, Ph.D.
U.S. EPA/OAQPS/AQAD
Air Quality Modeling Group (C439-01)
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

Phone: (919) 541-2703 Fax: (919) 541-0044

Email: thurman.james@epa.gov

From: Shappley, Ned

Sent: Tuesday, July 09, 2019 4:37 PM

**To:** Thurman, James < Thurman.James@epa.gov > **Cc:** Smith, Darcie < Smith.Darcie@epa.gov >

Subject: Document review

James,

Can I get your review on this document for the Willowbrook Risk Assessment document. Please edit as necessary.

**Thanks** 

Ned Shappley | USEPA | OAQPS | AQAD | Measurement Technology Group 109 TW Alexander Drive (E143-02) | Research Triangle Park, NC 27711

email: shappley.ned@epa.gov | Phone (919)541-7903 | Mobile (919)665-9903

From: Shappley, Ned [Shappley.Ned@epa.gov]

**Sent**: 7/1/2019 9:18:46 PM

To: Morris, Mark [Morris.Mark@epa.gov]

CC: Smith, Darcie [Smith.Darcie@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: Revised language

Attachments: Ethylene oxide emission rates (summary).docx

Mark,

A couple of revisions to my language for your risk assessment document. I finished my second draft of my appendix and I need to meet with our technical editor (Robin Segall) to discuss the changes. I plan to forward to James for his review tomorrow afternoon.

Thanks and let me know if you have any questions, Ned

Ned Shappley | USEPA|OAQPS|AQAD|Measurement Technology Group 109 TW Alexander Drive (E143-02) | Research Triangle Park, NC 27711 email: <a href="mailto:shappley.ned@epa.gov">shappley.ned@epa.gov</a> | Phone (919)541-7903 | Mobile (919)665-9903

From: Smith, Darcie [Smith.Darcie@epa.gov]

**Sent**: 5/22/2019 1:41:14 PM

**To**: Rimer, Kelly [Rimer.Kelly@epa.gov]; Morris, Mark [Morris.Mark@epa.gov]

**Subject**: RE: Sterigenics risk assessment for Wehrum 05 22 19.docx **Attachments**: Sterigenics risk assessment for Wehrum 05 22 19\_dps.docx

Darcie Smith U.S. EPA/OAQPS/ATAG

919.541.2076

smith.darcie@epa.gov

From: Rimer, Kelly

Sent: Wednesday, May 22, 2019 9:18 AM

To: Morris, Mark < Morris. Mark@epa.gov>; Smith, Darcie < Smith. Darcie@epa.gov>

Subject: Sterigenics risk assessment for Wehrum 05 22 19.docx

Would you guys have a minute to look at this for show stoppers/ I want ot send to Mike by 9:45. He will send to Bill

From: Morris, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=37BE72ADDC7B464CA5C5942501F7495B-MMORRIS]

**Sent**: 5/22/2019 11:52:10 AM

**To**: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: revised pager

Attachments: Sterigenics risk assessment summary v2 MarkM.docx

Mark Morris USEPA Mailcode C539-02 109 TW Alexander Drive RTP, NC 27711 (919) 541-5416 morris.mark@epa.gov

From: Morris, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=37BE72ADDC7B464CA5C5942501F7495B-MMORRIS]

**Sent**: 5/21/2019 12:58:44 PM

To: Rimer, Kelly [Rimer.Kelly@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

Subject: RE: Willowbrook pager

Attachments: Sterigenics risk assessment summary v2 MarkM.docx

#### Added risk results...

Mark Morris USEPA Mailcode C539-02 109 TW Alexander Drive RTP, NC 27711 (919) 541-5416 morris.mark@epa.gov

From: Rimer, Kelly

Sent: Monday, May 20, 2019 4:09 PM

To: Morris, Mark < Morris. Mark@epa.gov>; Smith, Darcie < Smith. Darcie@epa.gov>

Subject: FW: Willowbrook pager

From: Terry, Sara

Sent: Monday, May 20, 2019 9:06 AM

To: Davis, Alison < Davis. Alison@epa.gov >
Cc: Rimer, Kelly < Rimer. Kelly@epa.gov >

Subject: Willowbrook pager

Attached is a first cut at a plain language of the risk assessment for the public meeting.

Sara

From: Morris, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=37BE72ADDC7B464CA5C5942501F7495B-MMORRIS]

**Sent**: 7/25/2019 8:11:47 PM **To**: sking1644@yahoo.com

Subject: Draft doc

Attachments: RA rpt for Sterigenics Willowbrook IL 7\_25\_19.docx

Mark Morris USEPA Mailcode C539-02 109 TW Alexander Drive RTP, NC 27711 (919) 541-5416 morris.mark@epa.gov

From: Ward, Hillary [Ward.Hillary@epa.gov]

**Sent**: 5/7/2019 2:58:18 PM

To: Rimer, Kelly [Rimer.Kelly@epa.gov]
Subject: Re: EtO Briefing for OAR Visit

5/14

Sent from my iPhone

On May 7, 2019, at 8:19 AM, Rimer, Kelly < Rimer, Kelly@epa.gov > wrote:

Hi Hillary when is the OAR visit?

From: Ward, Hillary

Sent: Monday, May 06, 2019 3:39 PM

To: Weinstock, Lewis < Weinstock. Lewis@epa.gov>; Sasser, Erika < Sasser. Erika@epa.gov>; Jones, Rhea

<Jones.Rhea@epa.gov>; Lassiter, Penny <Lassiter.Penny@epa.gov>; South, Peter

<South.Peter@epa.gov>

Cc: Witt, Jon < Witt.Jon@epa.gov>; Rimer, Kelly < Rimer.Kelly@epa.gov>

Subject: EtO Briefing for OAR Visit

Hi everyone,

The following item will be added to the agenda for OAR's visit:

EtO Update: Risk Assessment and Regulatory Actions

Mike was interested in a briefing for OAR that covered the sterilizer rules and the risk assessment. Lew thought we could fold in the Willowbrook update as well. I'll block 45 minutes to 1 hour. Please let me know if you have concerns about the topic or meeting time.

Hillary Ward USEPA, Office of Air Quality Planning and Standards (919)541-3154

**Sent**: 5/16/2019 7:46:52 PM

To: Terry, Sara [Terry.Sara@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

**Subject**: RE: Draft Assessment Pager

Attachments: Sterigenics risk assessment summary v1kr edits.docx

I think this is a good start. Thanks so much for putting pen to paper (so to speak)

I had time to make a couple quick suggestions. I think it can go to PACS to get their input. We can finish it early next week.

# Kelly

From: Terry, Sara

Sent: Thursday, May 16, 2019 3:02 PM

To: Rimer, Kelly <Rimer.Kelly@epa.gov>; Smith, Darcie <Smith.Darcie@epa.gov>

Subject: Draft Assessment Pager

For your review, ideally today 😊

Sara

From: Rimer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=123A21A46D0E4E53A590798CDCC3FB47-KRIMER]

**Sent**: 5/25/2019 12:43:41 AM

To: Smith, Darcie [Smith.Darcie@epa.gov]; Mckelvey, Laura [Mckelvey.Laura@epa.gov]; Shappley, Ned

[Shappley.Ned@epa.gov]

**Subject**: Kelly's Presentation for your Review - if you want to

Attachments: Risk Assessment Results for Sterigenics - Willowbrook V2.pptx

Hi-

If you want to review, please do so by 2 pm tomorrow – earlier is better.

Don't worry about reviewing the speaker notes, they are in progress. But please if you have something you think I should say, please let me know.

The maps will change, but please provide your comments on

From: Davis, Alison [Davis.Alison@epa.gov]

**Sent**: 5/22/2019 12:44:20 PM

To: Rimer, Kelly [Rimer.Kelly@epa.gov]; Terry, Sara [Terry.Sara@epa.gov]

Subject: Reworked pager -- Sterigenics risk assessment summary v3.docx

Attachments: Sterigenics risk assessment summary v3.docx

Hey – I reworked this in light of the class I took yesterday. There are some comments/questions in yellow.

Thanks.

Alison

From: Jennifer McConahy [ Ex. 6 Personal Privacy (PP)

Sent: 8/14/2019 11:22:39 PIVI

To: Koerber, Mike [Koerber.Mike@epa.gov]

CC: Margaret Donnell [Margaret.Donnell@hiscox.com]; Rimer, Kelly [Rimer.Kelly@epa.gov]; Davis, Alison

[Davis.Alison@epa.gov]

Subject: Re: (EXT) Re: FW: EPA Report

## Mike-

I beg to differ... I sat in a meeting where multiple EPA staff agreed that the maps were misleading, and agreed to correct the map, even as fast as the next day for the community forum. The current map looks like the risk just drops off after the dark brown, when in fact the risk went out for miles. The surrounding communities deserve to have an accurate visual as to their risk going forward with their health.n More school buildings would be included, etc. I expect the map to reflect the risk, and it doesn't. Jen

On Wed, Aug 14, 2019 at 6:22 PM Koerber, Mike < Koerber. Mike@epa.gov > wrote:

The report reflects the information presented at the public meeting. Although we did not prepare any new maps, we did provide risk levels as a function of distance in the text of the report. I believe that is responsive to questions we received at the meeting.

Mike

Sent from my iPhone

On Aug 14, 2019, at 6:40 PM, Margaret Donnell < Margaret. Donnell @ Ex. 8 Personal Privacy (PP) wrote:

I agree with Jen. The new map was supposed to break down the risk beyond the 100 in 1m mark. Can you advise why that was not done and perhaps what the hold up was all these months if we received nothing other than what was provided in May?

Thank you,

Margie Donnell, Esq.
Sr. Claims Counsel - Professions
Architects & Engineers
Direct: | Ex. 6 Personal Privacy (PP) |

From: Jennifer McConahy < Ex. 6 Personal Privacy (PP)
Sent: Wednesday, August 14, 2019 5.11 Five

To: "Koerber, Mike" < Koerber. Mike@epa.gov>

CC: Margaret Donnell < Margaret. Donnell @ Ex. 6 Personal Privacy (PP)

Subject: (EXT) Re: FW: EPA Report

Thanks Mike-

Upon first glance, the maps were not updated to reflect risk beyond 100-200 cases per million. Why was this not done? I believe we spoke about it at the pre-meeting for the community forum and at the forum and EPA agreed to adjust the map. Thanks-Jen
On Wed, Aug 14, 2019 at 4:22 PM Koerber, Mike < Koerber.Mike@epa.gov > wrote:
FYI
From: Koerber, Mike Sent: Wednesday, August 14, 2019 5:22 PM To: Doug Pollock < DPOLLOCK@BURR-RIDGE.GOV >; Evan Walter < EWalter@burr-ridge.gov >; Gayle Neal < gneal@willowbrook.il.us >; John Durocher < jdurocher@indianheadpark-il.gov >; Tom Hinshaw < thinshaw@indianheadpark-il.gov >; Victor Simon < Ex. 6 Personal Privacy (PP) ; Frank Trilla < ftrilla@willowbrook.il.us > Subject: EPA Report
Today, we posted the final Risk Assessment Report for the Sterigenics facility in Willowbrook, Illinois. This report documents in detail the steps taken to estimate risk from ethylene oxide emissions from the facility. The conclusions in the report are the same as those presented at a public meeting in Burr Ridge, Illinois on May 29, 2019.
www.epa.gov/il/risk-assessment-report-sterigenics-facility-willowbrook-il
Please let me know if you have any questions.
Mike
Michael Koerber
Deputy Director
Office of Air Quality Planning and Standards
(919) 541-5557

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From: Terry, Sara [Terry.Sara@epa.gov]

**Sent**: 5/21/2019 9:38:48 PM

To: Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: Risk Assessment ppt

Attachments: Risk Assessment Results for Sterigencs- Willowbrook.pptx

If you want to think about this tonight go ahead, but I'd like to spend more time tomorrow cross walking this with yesterday's presentation, as well as some other material I have. But, it's a start...

Sara

From: Smith, Darcie [Smith.Darcie@epa.gov]

**Sent**: 2/14/2019 8:41:37 PM

To: Mozingo, Kristal [Mozingo.Kristal@epa.gov]

CC: Sasser, Erika [Sasser.Erika@epa.gov]; Terry, Sara [Terry.Sara@epa.gov]; Jones, Rhea [Jones.Rhea@epa.gov]; Rimer,

Kelly [Rimer.Kelly@epa.gov]

**Subject**: Pager for tomorrow's 3:30 with Bill Wehrum on EtO **Attachments**: EtO Update Pager for Wehrum Feb 15 2019.docx

Hi Kristal -

Here is the pager for tomorrow. Can you please forward to the appropriate people?

Thanks,

Darcie

Darcie Smith
U.S. EPA/OAQPS/ATAG

919.541.2076

⊠ smith.darcle@epa.gov

From: Tim Halik [thalik@willowbrook.il.us]

**Sent**: 1/30/2019 1:33:48 PM

To: Rimer, Kelly [Rimer.Kelly@epa.gov]

Subject: Willowbrook: Letter to USEPA RE: RTR

Attachments: ATT00001.txt; 19.01.29- Letter to EPA opposing RTR on HCL that undermines ETO risk assessment.pdf

Kelly -

I'm glad you're now back, and hope you are catching up on work.

We were forwarded the attached letter sent to the US EPA from US elected officials pertaining to a RTR on Hydrochloric Acid the EPA apparently transmitted to the Office of Management and Budget before the holidays.

Although we have tried, we unfortunately are not in regular communication with the US elected officials that sent the letter. We do not fully understand the issue that they state the RTR action created, of which they oppose. Would you mind explaining their concerns to me so that we can attempt to stay on top of all matters affecting the Willowbrook EtO issue?

Thank you.

### **Tim Halik**

Village Administrator Village of Willowbrook 835 Midway Drive Willowbrook, IL 60527

Office (direct): 630.920.2261

Fax: 630.323.0787

E-mail: thalik@willowbrook.il.us Web: www.willowbrookil.org



## January 29, 2019

## VIA ELECTRONIC DELIVERY

The Honorable Andrew Wheeler Acting Administrator and Deputy Administrator U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW Washington, D.C. 20460

Dear Acting Administrator Wheeler:

We write in response to the U.S. Environmental Protection Agency's (EPA) Residual Risk and Technology Assessment (RTR) on Hydrochloric Acid that EPA transmitted to the Office of Management and Budget with little public notice or congressional notification right before the holidays on December 20, 2018. As you know, EPA is required to publish RTRs for a variety of hazards. What is unusual in this specific RTR is that it includes the following language on a tangentially related chemical, ethylene oxide. Specifically, this RTR included the following request:

"These elevated risks are largely driven by an EPA risk value that was updated in late 2016. Although this updated risk value is also responsible for the elevated facility-wide risks calculated here, as noted earlier, these risks are due to emission sources that are not part of the HCl Production source category. Nevertheless, the EPA is interested in receiving public comments on the use of [ethylene oxide's] update[d] risk value for regulatory purposes."

The EPA is charged with safeguarding the environment and defending the public health of all Americans. We are alarmed that hidden inside the 103 page RTR was a troubling information request that appears to be a transparent invitation for the public—including chemical industries—to weaken EPA's forthcoming rules intended to protect Illinoisans and Americans throughout the Nation from elevated levels of cancer risk resulting from exposure to ethylene oxide (EtO). EPA has applied a consistent priority scheme to the sources of data it uses for its rulemakings. If EPA choose not to use its own assessment for determining inhalation risk values, it would contradict the Agency's longstanding policy and put many Americans at risk.

Furthermore, if accurate, this would represent an indefensible capitulation by EPA to the demands of the chemical industry. It is no secret that corporate special interests have been working to undermine and discredit EPA's IRIS program, specifically the recent scientific determination to revise the chemical's carcinogenicity of EtO to be 50 to 60 times more carcinogenic based on an improved model.

Since EPA updated the carcinogenic risk value of EtO, the American Chemistry Council (ACC) has lobbied EPA to withdraw its assessment. The chemical industry appears to be following the

playbook established by the fossil fuel industry when it sought to undermine climate change science and by tobacco companies when they attempted to cover up the danger of their products.

These efforts are bolstered by the presence of former employees at the highest levels of EPA. For example, Nancy Beck, a former lobbyist for ACC and current Deputy Assistant Administrator of Chemical Safety and Pollution Prevention, has long been a critic of EPA's IRIS program – even though EPA's program was praised by the National Academy of Science for its independence from the chemical industry and its systematic review process. Ms. Beck has also specifically criticized EPA's ethylene oxide risk assessment.

On behalf of our constituents and communities across the country, we strongly urge you to publicly commit to at least preserving, if not strengthening, EPA's current risk value of EtO. For several months, our constituents in and around Willowbrook and Lake County, Illinois have lived in fear that the air they breathe now, and breathed for decades, represents an elevated cancer risk. Their fears are grounded in the fact that facilities near them emitting EtO, a known carcinogen, had been vented well above levels deemed safe by EPA for decades.

In pursuit of transparency and to provide our constituents with confidence that EPA is working for the public good and not private profits, please provide our offices with a public commitment that EPA will defend and preserve the independent IRIS determination assessing the carcinogenicity of EtO. Equally important, we request that you publicly promise to rely on updated IRIS risk value determination to guide regulatory activities.

Defending the work of EPA's dedicated career civil servants by rejecting industry lobbyists' attempts to weaken these agency professionals' science-based assessments will go a long way towards increasing confidence in your leadership. Thank you in advance for your consideration of our request. If you have any questions about this request, please contact Radha Adhar from the Office of Senator Duckworth at Radha\_Adhar@duckworth.senate.gov or 202-224-2854.

Sincerely,

Tammy Vuckworth
United States Senator

Daniel W. Lipinski

United States Representative

Bill Foster

United States Representative

Richard J. Durbin United States Senator

Bradley S. Schneider

United States Representative

Sean Casten

United States Representative

From: Rimer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=123A21A46D0E4E53A590798CDCC3FB47-KRIMER]

**Sent**: 5/28/2019 6:20:30 PM

**To**: Kelly Rimer-Surles [OKRimer@Yahoo.com]

Subject: Risk Assessment Results for Sterigenics - Willowbrook V4 DRAFT 05 28 19.pptx

Attachments: Risk Assessment Results for Sterigenics - Willowbrook V4 DRAFT 05 28 19.pptx

From: Rimer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=123A21A46D0E4E53A590798CDCC3FB47-KRIMER]

**Sent**: 5/29/2019 9:09:03 PM

To: Davis, Alison [Davis.Alison@epa.gov]

**Subject**: Risk Assessment Results for Sterigenics - Willowbrook V9 FINAL.pptx **Attachments**: Risk Assessment Results for Sterigenics - Willowbrook V9 FINAL.pptx

Number 9

From: Rimer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=123A21A46D0E4E53A590798CDCC3FB47-KRIMER]

**Sent**: 8/22/2019 3:20:42 PM

To: Davis, Alison [Davis.Alison@epa.gov]

Subject: EtO

Attachments: Ethylene Oxide Update from EPA; RE: Stop Sterigenics "info"; RE: Stop Sterigenics "info"; Community Meeting re:

Sterigenics

From: Rimer, Kelly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=123A21A46D0E4E53A590798CDCC3FB47-KRIMER]

 Sent:
 10/5/2018 7:49:57 PM

 To:
 Frank [ระเธ Personal Privacy (PP)] [Daol.com]

**CC**: Ftrilla@willowbrook.il.us; thalik@willowbrook.il.us

**Subject**: Ethylene Oxide Update from EPA

## Mayor Trilla,

Below is a status and next steps update. We understand from the meeting last week that this is some of the information that you requested. Next week we will send answers to the questions we received along with information regarding the ATSDR letter.

We also plan to post this update to the EPA website identified below.

Also, I would be happy to share this information with anyone you would like me to.

I will reach out again to you on Tuesday to check in and to see if we can connect about the community meeting. Please do not hesitate to call if you have any questions.

Sincerely, Kelly Rimer U.S. EPA Office of Air Quality Planning & Standards 919-541-5368

#### Ethylene Oxide in Willowbrook: Status and Next Steps

# What is EPA doing to reduce ethylene oxide from the Sterigenics facility?

## What has been done to date:

Sterigenics has taken steps to further control ethylene oxide emissions from the Willowbrook facility and estimates that those controls have reduced ethylene oxide by about 92 percent.

On September 20 and 21 2018, a contractor hired by Sterigenics conducted stack tests to measure the actual emissions from the control devices at the facility. U.S. EPA and Illinois EPA experts were present to observe the tests.

#### What happens next:

- Once the final report from the stack test is complete, and delivered to U. S. EPA, the Agency will review the
  results to confirm how much ethylene oxide the pollution controls are reducing. EPA will that information to
  estimate *current* emissions from the Sterigenics facility.
- U.S. EPA needs the emissions estimates to help the agency determine how far any remaining ethylene oxide
  emissions will disperse and what the levels of ethylene oxide in the air nearby the facility are likely to be. EPA
  will determine this using a computer model.
- The information also will help EPA determine the best places to monitor the air for ethylene oxide in the area.
   EPA will work with local elected officials in the area as it develops its monitoring plan.
- Existing monitoring methods are not sensitive enough to detect ethylene oxide at all levels in the outdoor air.
   Because of this, EPA cannot use monitoring alone to determine the levels of ethylene oxide in the air around the facility.
- EPA will conduct a risk assessment for the Willowbrook area. This assessment will be more comprehensive than either NATA or the ATSDR analysis. It will be similar to the types of risk assessments EPA conducts when it is

reviewing its regulations for industries that emit air toxics to determine whether those rules need to be updated to improve protection of public health.

• EPA will update this information as this work proceeds on our NATA website at: https://www.epa.gov/il/sterigenics-willowbrook-facility

From: Shappley, Ned [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5FC7FDE372054AB5AC38F24B9072B73D-SHAPPLEY, N]

**Sent**: 7/10/2019 4:46:41 PM

To: Morris, Mark [Morris.Mark@epa.gov]; Smith, Darcie [Smith.Darcie@epa.gov]

CC: Thurman, James [Thurman.James@epa.gov]; Robin Segall (Segall.Robin@epa.gov) [Segall.Robin@epa.gov]; Johnson,

Steffan [johnson.steffan@epa.gov]; Rimer, Kelly [Rimer.Kelly@epa.gov]

**Subject**: Risk Assessment Appendix-Emission Estimates

Attachments: Development of EtO emission rates willowbrook 07 10 2019(FINAL).docx

#### Mark/Darcie,

Sorry for the delay, attached is the Appendix on emission estimates for the Willowbrook Risk Assessment, please let me know if you have any questions.

### Thanks,

Ned Shappley | USEPA | OAQPS | AQAD | Measurement Technology Group 109 TW Alexander Drive (E143-02) | Research Triangle Park, NC 27711 email: <a href="mailto:shappley.ned@epa.gov">shappley.ned@epa.gov</a> | Phone (919)541-7903 | Mobile (919)665-9903